covered by section 261 of Title 42, The Public Health and Welfare.

Section 236, act Jan. 19, 1929, ch. 82, § 16, 45 Stat. 1089, which provided penalties for the procuring of escape by inmates, is now covered by section 261 of Title 42, The Public Health and Welfare.

Section 237, act Jan. 19, 1929, ch. 82, § 17, 45 Stat. 1089, provided for the deportation of alien inmates who are entitled to a discharge from narcotic farms.

RENUMBERING OF REPEALING ACT

Section 611 of act July 1, 1944, which repealed this section, was renumbered 711 by act Aug. 13, 1946, ch. 956, § 5, 60 Stat. 1049, 713 by act Feb. 28, 1948, ch. 83, § 9 (b), 62 Stat. 47, and 813 by act July 30, 1956, ch. 779, § 3 (b), 70 Stat. 720.

Chapter 9.—FEDERAL FOOD, DRUG, AND COSMETIC ACT

SUBCHAPTER I.—SHORT TITLE

SUBCHAPTER II.—DEFINITIONS

SUBCHAPTER III.—PROHIBITED ACTS AND PENALTIES

SUBCHAPTER IV.—FOOD

SUBCHAPTER V.—DRUGS AND DEVICES

SUBCHAPTER I.—SHORT TITLE

§ 301. Short title.

This chapter may be cited as the Federal Food, Drug, and Cosmetic Act. (June 25, 1938, ch. 675, § 1, 52 Stat. 1040.)

EFFECTIVE DATE

Section 902 (a) of act June 25, 1938, provided that this section should take effect twelve months after June 25, 1938.

SUBCHAPTER II.—DEFINITIONS

§ 321. Definitions; generally.

For the purposes of this chapter—

(a) The term "Territory" means any Territory or possession of the United States, including the District of Columbia and excluding the Canal Zone.

(b) The term "interstate commerce" means (1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.

(c) The term "Department" means the Department of Health, Education, and Welfare.

(d) The term "Secretary" means the Secretary of Health, Education, and Welfare.

(e) The term "person" includes individual, partnership, corporation, and association.

(f) The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

(g) The term "drug" means (1) articles recognized in the official United States Pharmacopœia, official Homœopathic Pharmacopœia of the United States, or official National Formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for use as a component of any article specified in clauses (1), (2), or (3) of this subsection; but does not include devices or their components, parts, or accessories.

(h) The term "device" (except when used in paragraph (n) of this section and in sections 331 (i), 343 (f), 352 (c), and 362 (c)) of this title means instru-

ments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals.

(i) The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

(j) The term "official compendium" means the official United States Pharmacopœia, official Homœopathic Pharmacopœia of the United States, official National Formulary, or any supplement to any of them.

(k) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

(l) The term "immediate container" does not include package liners.

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

(n) If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual.

(o) The representation of a drug, in its labeling, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

(p) The term "new drug" means—

(1) Any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this chapter it was subject to former sections 1—5 and 7—15 of this title, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) Any drug the composition of which is such that such drug, as a result of investigations to determine its safety for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

(q) The term "pesticide chemical" means any substance which, alone, in chemical combination or in formulation with one or more other substances, is an "economic poison" within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act as now in force or as hereafter amended, and which is used in the production, storage, or transportation of raw agricultural commodities.

(r) The term "raw agricultural commodity" means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

(s) The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include—

(1) a pesticide chemical in or on a raw agricultural commodity; or

(2) a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; or

(3) any substance used in accordance with a sanction or approval granted prior to September 6, 1958, pursuant to this chapter, the Poultry Products Inspection Act (21 U. S. C. 451 and the following) or the Meat Inspection Act of March 4, 1907, as amended and extended.

(t) The term "safe", as used in paragraph (s) of this section and in section 348 of this title, has reference to the health of man or animal. (June 25, 1938, ch. 675, § 201, 52 Stat. 1041; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F. R. 2422, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F. R. 2053, 67 Stat. 631; July 22, 1954, ch. 559, § 1, 68 Stat. 511; Sept. 6, 1958, Pub. L. 85-929, § 2, 72 Stat. 1784.)

REFERENCES IN TEXT

Sections 1—5 and 7—15, referred to in subsec. (p) (1), constituted the Food and Drug Act of 1906, and were repealed by section 902 (a) of act June 25, 1938.

The Federal Insecticide, Fungicide, and Rodenticide Act, referred to in subsec. (q), is classified to sections 135—135k of Title 7, Agriculture.

The Poultry Products Inspection Act, referred to in the text of subsec. (s) (3) is classified to chapter 10 of this title.

The Meat Inspection Act of Mar. 4, 1907, referred to in the text of subsec. (s) (3) is classified to section 71 et seq. of this title.

AMENDMENTS

1958—Subsecs. (s) and (t) added by Pub. L. 85-929.

1954—Subsecs. (q) and (r) added by act July 22, 1954.

EFFECTIVE DATE OF 1958 AMENDMENT

Addition of subsecs. (s) and (t) as effective Sept. 6, 1953, see section 6 (a) of Pub. L. 85-929, set out as a note under section 342 of this title.

EFFECTIVE DATE OF 1954 AMENDMENT

Effective date of subsecs. (q) and (r), see note under section 342 of this title.

EFFECTIVE DATE

Section 902 (a) of act June 25, 1938, provided that this section should take effect twelve months after June 25, 1938.

SHORT TITLE

Section 1 of Pub. L. 85-929 provided that Pub. L. 85-929, which is classified to subsecs. (s) and (t) of this section, notes under sections 321, 342, and 451 of this title, section 348 of this title, note under section 2205 of Title 5, Executive Departments and Government Officers and Employees, and sections 331 (j), 342 (a), and 346 (a) of this title, and section 210 (g) of Title 42, The Public Health and Welfare, should be popularly known as the "Food Additives Amendment of 1958".

TRANSFER OF FUNCTIONS

All functions of the Federal Security Administrator were transferred to the Secretary of Health, Education, and Welfare and all agencies of the Federal Security Agency were transferred to the Department of Health, Education, and Welfare by section 5 of 1953 Reorg. Plan No. 1, set out as a note under section 623 of Title 5, Executive Departments and Government Officers and Employees. The Federal Security Agency and the office of Administrator were abolished by section 8 of 1953 Reorg. Plan No. 1.

The Food and Drug Administration, which is charged with the administration of this chapter, was transferred from the Department of Agriculture to the Federal Security Agency, to be administered under the direction and supervision of the Federal Security Administrator, by 1940 Reorg. Plan No. IV, § 12, set out as a note under section 133t of Title 5.

CROSS REFERENCES

Appropriations for purpose and administration of subsecs. (q) and (r), see section 346b of this title.

§ 321a. Same; butter.

For the purposes of this chapter "butter" shall be understood to mean the food product usually known as butter, and which is made exclusively from milk or cream, or both, with or without common salt, and with or without additional coloring matter, and containing not less than 80 per centum by weight of milk fat, all tolerances having been allowed for. (Mar. 4, 1923, ch. 268, 42 Stat. 1500; June 25, 1938, ch. 675, § 902 (a), 52 Stat. 1059.)

CODIFICATION

Section, which is not a provision of the Federal Food, Drug, and Cosmetic Act, which comprises this chapter, was formerly section 6 of this title. Act June 25, 1938, provided that the section should remain in force and effect and be applicable to the provisions of this chapter. See section 392 (a) of this title.

§ 321b. Same; package.

The word "package" where it occurs in this chapter shall include and shall be construed to include wrapped meats inclosed in papers or other materials as prepared by the manufacturers thereof for sale. (July 24, 1919, ch. 26, 41 Stat. 271; June 25, 1938, ch. 675, § 902 (a), 52 Stat. 1059.)

CODIFICATION

Section, which is not a provision of the Federal Food, Drug, and Cosmetic Act, which comprises this chapter, was formerly the last sentence of paragraph third of section 10 of this title, and was made applicable to that act by act June 25, 1938. See section 392 (a) of this title.

§ 321c. Same; nonfat dry milk; milk.

For the purposes of this chapter, nonfat dry milk is the product resulting from the removal of fat and water from milk, and contains the lactose, milk proteins, and milk minerals in the same relative proportions as in the fresh milk from which made. It contains not over 5 per centum by weight of moisture. The fat content is not over 1½ per centum by weight unless otherwise indicated.

The term "milk", when used herein, means sweet milk of cows. (Mar. 2, 1944, ch. 77, 58 Stat. 108; July 2, 1956, ch. 495, 70 Stat. 486.)

CODIFICATION

Section was not enacted as a part of the Federal Food, Drug, and Cosmetic Act, which comprises this chapter, but was made applicable thereto.

AMENDMENTS

1956—Act July 2, 1956, amended section, substituting "nonfat dry milk" for "nonfat dry milk solids or defatted milk solids".

SUBCHAPTER III.—PROHIBITED ACTS AND PENALTIES

§ 331. Prohibited acts.

The following acts and the causing thereof are prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 344 or 355 of this title.

(e) The refusal to permit access to or copying of any record as required by section 373 of this title.

(f) The refusal to permit entry or inspection as authorized by section 374 of this title.

(g) The manufacture within any Territory of any food, drug, device, or cosmetic that is adulterated or misbranded.

(h) The giving of a guaranty or undertaking referred to in section 333 (c) (2) of this title which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, or cosmetic; or the giving of a guaranty or undertaking referred to in section 333 (c) (3) of this title which guaranty or undertaking is false.

(i) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of sections 344, 346 (b), 354, 356, 357, or 364 of this title.

(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this chapter, any information acquired under authority of sections 344, 348, 355, 356, 357, or 374 of this title concerning any method or process which as a trade secret is entitled to protection.

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

(l) The using, on the labeling of any drug or in any advertising relating to such drug, of any representation or suggestion that an application with respect to such drug is effective under section 355 of this title, or that such drug complies with the provisions of such section.

(m) The sale or offering for sale of colored oleomargarine or colored margarine, or the possession or serving of colored oleomargarine or colored margarine in violation of subsections (b) or (c) of section 347 of this title.

(n) The using, in labeling, advertising or other sales promotion of any reference to any report or analysis furnished in compliance with section 374 of this title. (June 25, 1938, ch. 675, § 301, 52 Stat. 1042; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F. R. 2422, 54 Stat. 1237; Dec. 22, 1941, ch. 613, § 1, 55 Stat. 851; July 6, 1945, ch. 281, § 1, 59 Stat. 463; Mar. 10, 1947, ch. 16, § 1, 61 Stat. 11; June 24, 1948, ch. 613, § 1, 62 Stat. 582; Mar. 16, 1950, ch. 61, § 3 (b), 64 Stat. 20; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F. R. 2053, 67 Stat. 631; Aug. 7, 1953, ch. 350, § 2, 67 Stat. 477; Sept. 6, 1958, Pub. L. 85-929, § 5, 72 Stat. 1788.)

AMENDMENTS

1958—Subsec. (j) amended by Pub. L. 85-929, which inserted "348" following "344".

1953—Subsec. (n) added by act Aug. 7, 1953.

1950—Subsec. (m) added by act Mar. 16, 1950.

1948—Subsec. (k) amended by act June 24, 1948, by inserting "(whether or not the first sale)" so as to make it clear that this subsection is not limited to the case where the act occurs while the article is held for the first sale after interstate shipment, and extends coverage of subsection to acts which result in adulteration.

1947—Subsec. (j) amended by act Mar. 10, 1947, which inserted "356, 357" following "344, 355".

1945—Subsec. (i) amended by act July 6, 1945, which inserted "357" following "356".

1941—Subsec. (i) amended by act Dec. 22, 1941, which inserted reference to section 356.

EFFECTIVE DATE OF 1958 AMENDMENT

Amendment of subsec. (j) as effective Sept. 6, 1958, see section 6 (a) of Pub. L. 85-929, set out as note under section 342 of this title.

EFFECTIVE DATE OF 1950 AMENDMENT

Amendment of section by act Mar. 16, 1950, as effective July 1, 1950, see note set out under section 347 of this title.

EFFECTIVE DATE

Section 902 (a) of act June 25, 1938, provided that this section should take effect twelve months after June 25, 1938.

TRANSFER OF FUNCTIONS

All functions of the Federal Security Administrator were transferred to the Secretary of Health, Education, and Welfare and all agencies of the Federal Security Agency were transferred to the Department of Health, Education, and Welfare by section 5 of 1953 Reorg. Plan No. 1, set out as a note under section 623 of Title 5, Executive Departments and Government Officers and Employees. The Federal Security Agency and the office of Administrator were abolished by section 8 of 1953 Reorg. Plan No. 1.

See, also, note under section 321 of this title.

§ 332. Injunction proceedings.

(a) Jurisdiction of courts.

The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown, and subject to the provisions of section 381 (relating to notice to opposite party) of Title 28, to restrain violations of section 331 of this title, except paragraphs (e), (f), and (h)—(j) of said section.

(b) Violation of injunction.

In case of violation of an injunction or restraining order issued under this section, which also constitutes a violation of this chapter, trial shall be by the court, or, upon demand of the accused, by a jury. Such trial shall be conducted in accordance with the practice and procedure applicable in the case of proceedings subject to the provisions of section 387 of Title 28. (June 25, 1938, ch. 675, § 302, 52 Stat. 1043.)

REFERENCES IN TEXT

Section 381 of Title 28, as amended, referred to in subsec. (a), was repealed by act June 25, 1948, ch. 646, § 39, 62 Stat. 992, eff. Sept. 1, 1948, and is now covered by rule 65 of Federal Rules of Civil Procedure, Title 28, Appendix, Judiciary and Judicial Procedure.

Section 387 of Title 28, as amended, referred to in subsec. (b), was repealed by act June 25, 1948, ch. 645, § 21, 62 Stat. 862, and is now covered by section 402 of Title 18, Crimes and Criminal Procedure, and rule 42 (b) of the Federal Rules of Criminal Procedure, Title 18, Appendix.

EFFECTIVE DATE

Section 902 (a) of act June 25, 1938, provided that this section should take effect twelve months after June 25, 1938.

§ 333. Penalties.

(a) Violation of section 331 of this title.

Any person who violates any of the provisions of section 331 of this title shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine; but if the violation is committed after a conviction of such person under this section has become final such person shall be subject to imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine.

(b) Same; with intent to defraud or mislead.

Notwithstanding the provisions of subsection (a) of this section, in case of a violation of any of the

provisions of section 331 of this title with intent to defraud or mislead, the penalty shall be imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine.

(c) Exceptions in certain cases of good faith, etc.

No person shall be subject to the penalties of subsection (a) of this section, (1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the Secretary the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him; or (2) for having violated section 331 (a) or (d) of this title, if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 331 (a) of this title, that such article is not adulterated or misbranded, within the meaning of this chapter designating this chapter or to the effect, in case of an alleged violation of section 331 (d) of this title, that such article is not an article which may not, under the provisions of section 344 or 355 of this title, be introduced into interstate commerce; or (3) for having violated section 331 (a) of this title, where the violation exists because the article is adulterated by reason of containing a coal-tar color not from a batch certified in accordance with regulations promulgated by the Secretary under this chapter, if such person establishes a guaranty or undertaking signed by, and containing the name and address of, the manufacturer of the coal-tar color, to the effect that such color was from a batch certified in accordance with the applicable regulations promulgated by the Secretary under this chapter; or (4) for having violated section 331 (b), (c) or (k) by failure to comply with section 352 (f) of this title in respect to an article received in interstate commerce to which neither section 353 (a) nor 353 (b) (1) of this title is applicable, if the delivery or proffered delivery was made in good faith and the labeling at the time thereof contained the same directions for use and warning statements as were contained in the labeling at the time of such receipt of such article. (June 25, 1938, ch. 675, § 303, 52 Stat. 1043; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F. R. 2422, 54 Stat. 1237; Oct. 26, 1951, ch. 578, § 2, 65 Stat. 649; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F. R. 2053, 67 Stat. 631.)

AMENDMENTS

1951—Subsec. (c) (4) added by act Oct. 26, 1951.

EFFECTIVE DATE OF 1951 AMENDMENT

Section 3 of act Oct. 26, 1951, provided that the amendment of this section should take effect six months after Oct. 26, 1951.

EFFECTIVE DATE

Section 902 (a) of act June 25, 1938, provided that this section should take effect twelve months after June 25, 1938.

TRANSFER OF FUNCTIONS

All functions of the Federal Security Administrator were transferred to the Secretary of Health, Education, and Welfare and all agencies of the Federal Security Agency were transferred to the Department of Health, Education, and Welfare by section 5 of 1953 Reorg. Plan No. 1, set out as a note under section 623 of Title 5, Executive Departments and Government Officers and Employees. The Federal Security Agency and the office of Administrator were abolished by section 8 of 1953 Reorg. Plan. No. 1.

See, also, note under section 321 of this title.

CROSS REFERENCES

Furnishing of guaranties, applicability to raw agricultural commodities, see section 346a (n) of this title.

§ 334. Seizure.

(a) Grounds and jurisdiction.

Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of section 344 or 355 of this title, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found: *Provided, however,* That no libel for condemnation shall be instituted under this chapter, for any alleged misbranding if there is pending in any court a libel for condemnation proceeding under this chapter based upon the same alleged misbranding, and not more than one such proceeding shall be instituted if no such proceeding is so pending, except that such limitations shall not apply (1) when such misbranding has been the basis of a prior judgment in favor of the United States, in a criminal, injunction, or libel for condemnation proceeding under this chapter, or (2) when the Secretary has probable cause to believe from facts found, without hearing, by him or any officer or employee of the Department that the misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer. In any case where the number of libel for condemnation proceedings is limited as above provided the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district agreed upon by stipulation between the parties, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, to which the case shall be removed for trial.

(b) Procedure; multiplicity of pending proceedings.

The article shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by jury. When libel for condemnation proceedings under this section, involving the same claimant and the same issues of adulteration or

misbranding, are pending in two or more jurisdictions, such pending proceedings, upon application of the claimant seasonably made to the court of one such jurisdiction, shall be consolidated for trial by order of such court, and tried in (1) any district selected by the claimant where one of such proceedings is pending; or (2) a district agreed upon by stipulation between the parties. If no order for consolidation is so made within a reasonable time, the claimant may apply to the court of one such jurisdiction, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, in which all such pending proceedings shall be consolidated for trial and tried. Such order of consolidation shall not apply so as to require the removal of any case the date for trial of which has been fixed. The court granting such order shall give prompt notification thereof to the other courts having jurisdiction of the cases covered thereby.

(c) Availability of samples of seized goods prior to trial.

The court at any time after seizure up to a reasonable time before trial shall by order allow any party to a condemnation proceeding, his attorney or agent, to obtain a representative sample of the article seized and a true copy of the analysis, if any, on which the proceeding is based and the identifying marks or numbers, if any, of the packages from which the samples analyzed were obtained.

(d) Disposition of goods after decree of condemnation.

Any food, drug, device, or cosmetic condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States; but such article shall not be sold under such decree contrary to the provisions of this chapter or the laws of the jurisdiction in which sold: *Provided*, That after entry of the decree and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such article shall not be sold or disposed of contrary to the provisions of this chapter or the laws of any State or Territory in which sold, the court may by order direct that such article be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this chapter under the supervision of an officer or employee duly designated by the Secretary, and the expenses of such supervision shall be paid by the person obtaining release of the article under bond. If the article was imported into the United States and the person seeking its release establishes (1) that the adulteration, misbranding, or violation did not occur after the article was imported, and (2) that he had no cause for believing that it was adulterated, misbranded, or in violation before it was released from customs custody, the court may permit the article to be delivered to the owner for exportation in lieu of destruction upon a showing by the owner that all of the conditions of section 381 (d) of this title can and will be met: *Provided, however*, That the provisions of this sentence shall not apply where condemnation is based upon violation of section 342 (a) (1), (2), or (6), section 351 (a) (3), section 352 (j), or section 361 (a) or (d) of this title: *And provided further*, That where such exportation is made to the original foreign supplier, then clauses (1) and (2) of section 381 (d) of this title and the foregoing proviso shall not be applicable; and in all cases of exportation the bond shall be conditioned that the article shall not be sold or disposed of until the applicable conditions of section 381 (d) of this title have been met. Any article condemned by reason of its being an article which may not, under section 344 or 355 of this title, be introduced into interstate commerce, shall be disposed of by destruction.

(e) Costs.

When a decree of condemnation is entered against the article, court costs and fees, and storage and other proper expenses, shall be awarded against the person, if any, intervening as claimant of the article.

(f) Removal of case for trial.

In the case of removal for trial of any case as provided by subsection (a) or (b) of this section—

(1) The clerk of the court from which removal is made shall promptly transmit to the court in which the case is to be tried all records in the case necessary in order that such court may exercise jurisdiction.

(2) The court to which such case was removed shall have the powers and be subject to the duties, for purposes of such case, which the court from which removal was made would have had, or to which such court would have been subject, if such case had not been removed.

(June 25, 1938, ch. 675, § 304, 52 Stat. 1044; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F. R. 2422, 54 Stat. 1237; June 24, 1948, ch. 613, § 2, 62 Stat. 582; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F. R. 2053, 67 Stat. 631; Aug. 7, 1953, ch. 350, § 3, 67 Stat. 477; Aug. 31, 1957, Pub. L. 85-250, 71 Stat. 567.)

AMENDMENTS

1957—Subsec. (d) amended by Pub. L. 85-250 to permit, under certain circumstances, reexportation of articles condemned at places other than original port of entry.

1953—Subsec. (c) amended by act Aug. 7, 1953, to provide that a true copy of the analysis in any case shall be furnished the owner.

1948—Subsec. (a) amended by act June 24, 1948, by inserting "or while held for sale (whether or not the first sale) after shipment in interstate commerce" to make this subsection coextensive with section 331 (k) of this title.

EFFECTIVE DATE

Section 902 (a) of act June 25, 1938, provided that this section should take effect twelve months after June 25, 1938.

TRANSFER OF FUNCTIONS

All functions of the Federal Security Administrator were transferred to the Secretary of Health, Education, and Welfare and all agencies of the Federal Security Agency were transferred to the Department of Health, Education, and Welfare by section 5 of 1953 Reorg. Plan No. 1, set out as a note under section 623 of Title 5, Executive Departments and Government Officers and Employees. The Federal Security Agency and the office of

Administrator were abolished by section 8 of 1953 Reorg. Plan No. 1.

See, also, note under section 321 of this title.

§ 335. Hearing before report of criminal violation.

Before any violation of this chapter is reported by the Secretary to any United States attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding. (June 25, 1938, ch. 675, § 305, 52 Stat. 1045; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F. R. 2422, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F. R. 2053, 67 Stat. 631.)

EFFECTIVE DATE

Section 902 (a) of act June 25, 1938, provided that this section should take effect twelve months after June 25, 1938.

TRANSFER OF FUNCTIONS

All functions of the Federal Security Administrator were transferred to the Secretary of Health, Education, and Welfare and all agencies of the Federal Security Agency were transferred to the Department of Health, Education, and Welfare by section 5 of 1953 Reorg. Plan No. 1, set out as a note under section 623 of Title 5, Executive Departments and Government Officers and Employees. The Federal Security Agency and the office of Administrator were abolished by section 8 of 1953 Reorg. Plan No. 1.

See, also, note under section 321 of this title.

§ 336. Report of minor violations.

Nothing in this chapter shall be construed as requiring the Secretary to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of this chapter whenever he believes that the public interest will be adequately served by a suitable written notice or warning. (June 25, 1938, ch. 675, § 306, 52 Stat. 1045; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F. R. 2422, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F. R. 2053, 67 Stat. 631.)

EFFECTIVE DATE

Section 902 (a) of act June 25, 1938, provided that this section should take effect twelve months after June 25, 1938.

TRANSFER OF FUNCTIONS

All functions of the Federal Security Administrator were transferred to the Secretary of Health, Education, and Welfare and all agencies of the Federal Security Agency were transferred to the Department of Health, Education, and Welfare by section 5 of 1953 Reorg. Plan No. 1, set out as a note under section 623 of Title 5, Executive Departments and Government Officers and Employees. The Federal Security Agency and the office of Administrator were abolished by section 8 of 1953 Reorg. Plan No. 1.

See, also, note under section 321 of this title.

§ 337. Proceedings in name of United States; provision as to subpoenas.

All such proceedings for the enforcement, or to restrain violations, of this act shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any such proceeding. (June 25, 1938, ch. 675, § 307, 52 Stat. 1046; Sept. 3, 1954, ch. 1263, § 37, 68 Stat. 1239.)

AMENDMENTS

1954—Act Sept. 3, 1954, amended section to eliminate reference to former section 654 of Title 28 which has been repealed.

EFFECTIVE DATE

Section 902 (a) of act June 25, 1938, provided that this section should take effect twelve months after June 25, 1938.

SUBCHAPTER IV.—FOOD

§ 341. Definitions and standards for food.

Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container: *Provided*, That no definition and standard of identity and no standard of quality shall be established for fresh or dried fruits, fresh or dried vegetables, or butter, except that definitions and standards of identity may be established for avocadoes, cantaloupes, citrus fruits, and melons. In prescribing any standard of fill of container, the Secretary shall give due consideration to the natural shrinkage in storage and in transit of fresh natural food and to need for the necessary packing and protective material. In the prescribing of any standard of quality for any canned fruit or canned vegetable, consideration shall be given and due allowance made for the differing characteristics of the several varieties of such fruit or vegetable. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Secretary shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. Any definition and standard of identity prescribed by the Secretary for avocadoes, cantaloupes, citrus fruits, or melons shall relate only to maturity and to the effects of freezing. (June 25, 1938, ch. 675, § 401, 52 Stat. 1046; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F. R. 2422, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F. R. 2053, 67 Stat. 631; Apr. 15, 1954, ch. 143, § 1, 68 Stat. 54; Aug. 1, 1956, ch. 861, § 1, 70 Stat. 919.)

AMENDMENTS

1956—Act Aug. 1, 1956, amended section by designating provisions constituting subsec. (a) as entire section and by repealing subsec. (b), which provided the procedure for establishment of regulations and is now covered by section 371 (e) of this title.

1954—Subsec. (a), formerly entire section, was so designated by act Apr. 15, 1954.

Subsec. (b) added by act Apr. 15, 1954.

EFFECTIVE DATE

Section 902 (a) of act June 25, 1938, provided that this section should take effect twelve months after June 25, 1938.

SAVINGS CLAUSE

Section 3 of act Aug. 1, 1956, provided that: "In any case in which, prior to the enactment of this Act [Aug. 1, 1956], a public hearing has been begun in accordance with section 401 of the Federal Food, Drug, and Cosmetic Act [341 of this title] upon a proposal to issue, amend, or repeal any regulation contemplated by such section, or has been begun in accordance with section 701 (e) of such Act [section 371 (e) of this title] upon a proposal to issue, amend, or repeal any regulation contemplated by section 403 (j), 404 (a), 406 (a) or (b), 501 (b), 502 (d), 502 (h), 504 or 604 of such Act [section 343 (j), 344 (a), 346 (a) or (b), 351 (b), 352 (d), 352 (h), 354, or 364 of this title], the provisions of such section 401 or

701 (e), as the case may be, as in force immediately prior to the date of the enactment of this Act [Aug. 1, 1956], shall be applicable as though this Act [amending this section and section 371 (e) of this title] had not been enacted."

TRANSFER OF FUNCTIONS

All functions of the Federal Security Administrator were transferred to the Secretary of Health, Education, and Welfare and all agencies of the Federal Security Agency were transferred to the Department of Health, Education, and Welfare by section 5 of 1953 Reorg. Plan No. 1, set out as a note under section 623 of Title 5, Executive Departments and Government Officers and Employees. The Federal Security Agency and the office of Administrator were abolished by section 8 of 1953 Reorg. Plan No. 1.

See, also, note under section 321 of this title.

HEARINGS PENDING ON APRIL 15, 1954

Section 3 of act Apr. 15, 1954, provided: "In any case in which, prior to the date of the enactment of this Act [April 15, 1954], a public hearing has been begun, in accordance with section 701 (e) of the Federal Food, Drug, and Cosmetic Act [section 371 (e) of this title], upon a proposal to issue, amend, or repeal any regulation contemplated by section 401 of such Act [this section], the provisions of such Act [this chapter], as in force immediately prior to the date of the enactment of this Act, shall be applicable as though this Act had not been enacted."

§ 342. Adulterated food.

A food shall be deemed to be adulterated—

(a) Poisonous, insanitary, etc., ingredients.

(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) (A) if it bears or contains any added poisonous or added deleterious substance (except a pesticide chemical in or on a raw agricultural commodity and except a food additive) which is unsafe within the meaning of section 346 of this title, or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 346a (a) of this title, or (C) if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 348 of this title: *Provided,* That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 346a of this title and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 346 and 348 of this title, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity; (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title.

(b) Absence, substitution, or addition of constituents.

(1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

(c) Uncertified coal tar coloring.

If it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 346 of this title: *Provided,* That this subsection shall not apply to citrus fruit bearing or containing a coal-tar color if application for listing of such color has been made under this chapter and such application has not been acted on by the Secretary, if such color was commonly used prior to the enactment of this chapter for the purpose of coloring citrus fruit: *Provided further,* That this subsection shall not apply to oranges meeting minimum maturity standards established by or under the laws of the States in which the oranges were grown and not intended for processing (other than oranges designated by the trade as "packing house elimination"), the skins of which have been colored at any time prior to March 1, 1959, with the coal-tar color certified prior to the enactment of this proviso as F. D. & C. Red 32, or certified after such enactment as External D. & C. Red 14 in accordance with section 21, Code of Federal Regulations, part 9: *And provided further,* That the preceding proviso shall have no further effect if prior to March 1, 1959, another coal-tar color suitable for coloring oranges is listed under section 346 of this title.

(d) Confectionery containing alcohol or nonnutritive substance.

If it is confectionery, and it bears or contains any alcohol or nonnutritive article or substance except harmless coloring, harmless flavoring, harmless resinous glaze not in excess of four-tenths of 1 per centum, natural gum, and pectin: *Provided,* That this subsection shall not apply to any confectionery by reason of its containing less than one-half of 1 per centum by volume of alcohol derived solely from the use of flavoring extracts, or to any chewing gum by reason of its containing harmless nonnutritive masticatory substances.

(e) Oleomargarine containing filthy, putrid, etc., matter.

If it is oleomargarine or margarine or butter and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed

substance, or such oleomargarine or margarine or butter is otherwise unfit for food. (June 25, 1938, ch. 675, § 402, 52 Stat. 1046; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F. R. 2422, 54 Stat. 1237; Mar. 16, 1950, ch. 61, § 3 (d), 64 Stat. 20; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F. R. 2053, 67 Stat. 631; July 22, 1954, ch. 559, § 2, 68 Stat. 511; July 9, 1956, ch. 530, 70 Stat. 512; Sept. 6, 1958, Pub. L. 85–929, § 3 (a), (b), 72 Stat. 1784.)

AMENDMENTS

1958—Subsec. (a) amended by Pub. L. 85–929 which, among other changes, inserted clause (2) (C) relating to food additive unsafe within the meaning of section 348 of this title, and to pesticide chemical, and added clause (7), relating to radiated food.

1956—Subsec. (c) amended by act July 9, 1956, which added second proviso relating to the coloring of oranges.

1954—Subsec. (a) (2) amended by act July 22, 1954, to provide, in the case of any raw agricultural commodity bearing or containing a pesticide chemical, that such commodity shall be deemed to be adulterated if such pesticide chemical is unsafe within the meaning of section 346a of this title.

1956—Subsec. (e) added by act Mar. 16, 1950.

EFFECTIVE DATE OF 1958 AMENDMENT

Section 6 of Pub. L. 85–929 provided that:

"(a) Except as provided in subsections (b) and (c) of this section, this Act [sections 321 (s) and (t), 321 note, 451 note, and section 343 of this title, section 2205 note of Title 5, Executive Departments and Government Officers and Employees, and sections 331 (j) of this title and 210 (g) of Title 42, the Public Health and Welfare] shall take effect on the date of its enactment. [Sept. 6, 1958].

"(b) Except as provided in subsection (c) of this section, section 3 of this Act [amending subsec. (a) of this section and section 346 (a) of this title] shall take effect on the one hundred and eightieth day after the date of enactment of this Act [Sept. 6, 1958].

"(c) With respect to any particular commercial use of a food additive, if such use was made of such additive before January 1, 1958, section 3 of this Act [amending subsec. (a) of this section and section 346 (a) of this title] shall take effect—

"(1) Either (A) one year after the effective date established in subsection (b) of this section, or (B) at the end of such additional period (but not later than two years from such effective date established in subsection (b)) as the Secretary of Health, Education, and Welfare may prescribe on the basis of a finding that such extension involves no undue risk to the public health and that conditions exist which necessitate the prescribing of such an additional period, or

"(2) on the date on which an order with respect to such use under section 409 of the Federal Food, Drug, and Cosmetic Act [section 348 of this title] becomes effective,

whichever date first occurs."

EFFECTIVE DATE OF 1954 AMENDMENT

Section 5 of act July 22, 1954, provided that:

"This Act [sections 321 (q), (r), 342 (a) (2), 346a and 346b of this title] shall take effect upon the date of its enactment [July 22, 1954], except that with respect to pesticide chemicals for which tolerances or exemptions have not been established under section 408 of the Federal Food, Drug, and Cosmetic Act [section 346a of this title], the amendment to section 402 (a) of such Act [subsec. (a) (2) of this section] made by section 2 of this Act shall not be effective—

"(1) for the period of one year following the date of the enactment of this Act [July 22, 1954]; or

"(2) for such additional period following such period of one year, but not extending beyond two years after the date of the enactment of this Act [July 22, 1954], as the Secretary of Health, Education, and Welfare may prescribe on the basis of a finding that conditions exist which necessitate the prescribing of such additional period."

EFFECTIVE DATE OF 1950 AMENDMENT

Amendment of section by act Mar. 16, 1950, as effective July 1, 1950, see note set out under section 347 of the title.

EFFECTIVE DATE

Section 902 (a) of act June 25, 1938, provided that this section should take effect twelve months after June 25, 1938. Act June 23, 1939, ch. 242, § 1, 53 Stat. 853, provided that the effective date of subsection (c) should be postponed until January 1, 1940.

TRANSFER OF FUNCTIONS

All functions of the Federal Security Administrator were transferred to the Secretary of Health, Education, and Welfare and all agencies of the Federal Security Agency were transferred to the Department of Health, Education, and Welfare by section 5 of 1953 Reorg. Plan No. 1, set out as a note under section 623 of Title 5, Executive Departments and Government Officers and Employees. The Federal Security Agency and the office of Administrator were abolished by section 8 of 1953 Reorg. Plan No. 1.

See, also, note under section 321 of this title.

CROSS REFERENCES

Appropriations for establishing tolerances for pesticide chemicals, see section 346b of this title.

§ 343. Misbranded food.

A food shall be deemed to be misbranded—

(a) False or misleading label.

If its labeling is false or misleading in any particular.

(b) Offer for sale under another name.

If it is offered for sale under the name of another food.

(c) Imitation of another food.

If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.

(d) Misleading container.

If its container is so made, formed, or filled as to be misleading.

(e) Package form.

If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (2) of this subsection reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(f) Prominence of information on label.

If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(g) Representation as to definition and standard of identity.

If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 341

of this title, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

(h) Representation as to standards of quality and fill of container.

If it purports to be or is represented as—

(1) a food for which a standard of quality has been prescribed by regulations as provided by section 341, and its quality falls below such standard, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard; or

(2) a food for which a standard or standards of fill of container have been prescribed by regulations as provided by section 341 of this title, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard.

(i) Label where no representation as to definition and standard of identity.

If it is not subject to the provisions of subsection (g) of this section unless its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient; except that spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings, and colorings without naming each: *Provided*, That, to the extent that compliance with the requirements of clause (2) of this subsection is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

(j) Representation for special dietary use.

If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses.

(k) Artificial flavoring, etc.; exception of articles from subsections (g), (i), and (k).

If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact: *Provided*, That to the extent that compliance with the requirements of this subsection is impracticable, exemptions shall be established by regulations promulgated by the Secretary. The provisions of this subsection and subsections (g) and (i) of this section with respect to artificial coloring shall not apply in the case of butter, cheese, or ice cream. (June 25, 1938, ch. 675, § 403, 52 Stat. 1047; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F. R. 2422, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F. R. 2053, 67 Stat. 631.)

EFFECTIVE DATE

Section 902 (a) of act June 25, 1938, provided that this section should take effect twelve months after June 25, 1938. Act June 23, 1939, ch. 242, § 1, 53 Stat. 853, provided that the effective date of subsections (e) (1), (g), (h), (i), (j), and (k) should be postponed until January 1, 1940

TRANSFER OF FUNCTIONS

All functions of the Federal Security Administrator were transferred to the Secretary of Health, Education, and Welfare and all agencies of the Federal Security Agency were transferred to the Department of Health, Education, and Welfare by section 5 of 1953 Reorg. Plan No. 1, set out as a note under section 623 of Title 5, Executive Departments and Government Officers and Employees. The Federal Security Agency and the office of Administrator were abolished by section 8 of 1953 Reorg. Plan No. 1.

See, also, note under section 321 of this title.

§ 344. Emergency permit control.

(a) Conditions on manufacturing, processing, etc., as health measure.

Whenever the Secretary finds after investigation that the distribution in interstate commerce of any class of food may, by reason of contamination with micro-organisms during the manufacture, processing, or packing thereof in any locality, be injurious to health, and that such injurious nature cannot be adequately determined after such articles have entered interstate commerce, he then, and in such case only, shall promulgate regulations providing for the issuance, to manufacturers, processors, or packers of such class of food in such locality, of permits to which shall be attached such conditions governing the manufacture, processing, or packing of such class of food, for such temporary period of time, as may be necessary to protect the public health; and after the effective date of such regulations, and during such temporary period, no person shall introduce or deliver for introduction into interstate commerce any such food manufactured, processed, or packed by any such manufacturer, processor, or packer unless such manufacturer, processor, or packer holds a permit issued by the Secretary as provided by such regulations.

(b) Violation of permit; suspension and reinstatement.

The Secretary is authorized to suspend immediately upon notice any permit issued under authority of this section if it is found that any of the conditions of the permit have been violated. The holder of a permit so suspended shall be privileged at any time to apply for the reinstatement of such permit, and the Secretary shall, immediately after prompt hearing and an inspection of the establishment, reinstate such permit if it is found that adequate measures have been taken to comply with and maintain the conditions of the permit, as originally issued or as amended.

(c) Inspection of permit-holding establishments.

Any officer or employee duly designated by the Secretary shall have access to any factory or establishment, the operator of which holds a permit from the Secretary, for the purpose of ascertaining whether or not the conditions of the permit are being complied with, and denial of access for such inspection shall be ground for suspension of the permit until such access is freely given by the operator. (June 25, 1938, ch. 675, § 404, 52 Stat. 1048; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F. R. 2422, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F. R. 2053, 67 Stat. 631.)

EFFECTIVE DATE

Section 902 (a) of act June 25, 1938, provided that this section should take effect twelve months after June 25, 1938.

TRANSFER OF FUNCTIONS

All functions of the Federal Security Administrator were transferred to the Secretary of Health, Education, and Welfare and all agencies of the Federal Security Agency were transferred to the Department of Health, Education, and Welfare by section 5 of 1953 Reorg. Plan No. 1, set out as a note under section 623 of Title 5, Executive Departments and Government Officers and Employees. The Federal Security Agency and the office of Administrator were abolished by section 8 of 1953 Reorg. Plan No. 1.

See, also, note under section 321 of this title.

§ 345. Regulations making exemptions.

The Secretary shall promulgate regulations exempting from any labeling requirement of this chapter (1) small open containers of fresh fruits and fresh vegetables and (2) food which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such food is not adulterated or misbranded under the provisions of this chapter upon removal from such processing, labeling, or repacking establishment. (June 25, 1938, ch. 675, § 405, 52 Stat. 1049; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F. R. 2422, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F. R. 2053, 67 Stat. 631.)

EFFECTIVE DATE

Section 902 (a) of act June 25, 1938, provided that this section should take effect twelve months after June 25, 1938.

TRANSFER OF FUNCTIONS

All functions of the Federal Security Administrator were transferred to the Secretary of Health, Education, and Welfare and all agencies of the Federal Security Agency were transferred to the Department of Health, Education, and Welfare by section 5 of 1953 Reorg. Plan No. 1, set out as a note under section 623 of Title 5, Executive Departments and Government Officers and Employees. The Federal Security Agency and the office of Administrator were abolished by section 8 of 1953 Reorg. Plan No. 1.

See, also, note under section 321 of this title.

§ 346. Tolerances for poisonous ingredients in food and certification of coal-tar colors for food.

(a) Regulations for tolerating unavoidable poisonous ingredients.

Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2) (A) of section 342 (a) of this title; but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2) (A) of section 342 (a) of this title. While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 342 (a) of this title. In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

(b) Regulations for coal-tar colors.

The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmless diluents. (June 25, 1938, ch. 675, § 406, 52 Stat. 1049; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F. R. 2422, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F. R. 2053, 67 Stat. 631; Sept. 6, 1958, Pub. L. 85-929, § 3 (c), 72 Stat. 1785.)

AMENDMENTS

1958—Subsec. (a) amended by Pub. L. 85-929, which substituted "clause (2) (A)" for "clause (2)" in first sentence.

EFFECTIVE DATE OF 1958 AMENDMENT

Effective date of 1953 amendment of subsec. (a), see section 6 (h), (c) of Pub. L. 85-929, set out as a note under section 342 of this title.

EFFECTIVE DATE

Section 902 (a) of act June 25, 1938, provided that this section should take effect twelve months after June 25, 1938.

TRANSFER OF FUNCTIONS

All functions of the Federal Security Administrator were transferred to the Secretary of Health, Education, and Welfare and all agencies of the Federal Security Agency were transferred to the Department of Health, Education, and Welfare by section 5 of 1953 Reorg. Plan No. 1, set out as a note under section 623 of Title 5, Executive Departments and Government Officers and Employees. The Federal Security Agency and the office of Administrator were abolished by section 8 of 1953 Reorg. Plan No. 1.

See, also, note under section 321 of this title.

CROSS REFERENCES

Pesticide chemical regulations, see section 346a of this title.

§ 346a. Tolerances for pesticide chemicals in or on raw agricultural commodities.

(a) Conditions of safety.

Any poisonous or deleterious pesticide chemical, or any pesticide chemical which is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of pesticide chemicals, as safe for use, added to a raw agricultural commodity, shall be deemed unsafe for the purposes of the application of clause (2) of section 342 (a) of this title unless—

(1) a tolerance for such pesticide chemical in or on the raw agricultural commodity has been prescribed by the Secretary of Health, Education, and Welfare under this section and the quantity of such pesticide chemical in or on the raw agricultural commodity is within the limits of the tolerance so prescribed; or

(2) with respect to use in or on such raw agricultural commodity, the pesticide chemical has been exempted from the requirement of a tolerance by the Secretary under this section.

While a tolerance or exemption from tolerance is in effect for a pesticide chemical with respect to any raw agricultural commodity, such raw agricultural

commodity shall not, by reason of bearing or containing any added amount of such pesticide chemical, be considered to be adulterated within the meaning of clause (1) of section 342 (a) of this title.

(b) Establishment of tolerances.

The Secretary shall promulgate regulations establishing tolerances with respect to the use in or on raw agricultural commodities of poisonous or deleterious pesticide chemicals and of pesticide chemicals which are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of pesticide chemicals, as safe for use, to the extent necessary to protect the public health. In establishing any such regulation, the Secretary shall give appropriate consideration, among other relevant factors, (1) to the necessity for the production of an adequate, wholesome, and economical food supply; (2) to the other ways in which the consumer may be affected by the same pesticide chemical or by other related substances that are poisonous or deleterious; and (3) to the opinion of the Secretary of Agriculture as submitted with a certification of usefulness under subsection (l) of this section. Such regulations shall be promulgated in the manner prescribed in subsection (d) or (e) of this section. In carrying out the provisions of this section relating to the establishment of tolerances, the Secretary may establish the tolerance applicable with respect to the use of any pesticide chemical in or on any raw agricultural commodity at zero level if the scientific data before the Secretary does not justify the establishment of a greater tolerance.

(c) Exemptions.

The Secretary shall promulgate regulations exempting any pesticide chemical from the necessity of a tolerance with respect to use in or on any or all raw agricultural commodities when such a tolerance is not necessary to protect the public health. Such regulations shall be promulgated in the manner prescribed in subsection (d) or (e) of this section.

(d) Regulations pursuant to petition; publication of notice; time for issuance; referral to advisory committees; effective date; hearings.

(1) Any person who has registered, or who has submitted an application for the registration of, an economic poison under the Federal Insecticide, Fungicide, and Rodenticide Act may file with the Secretary of Health, Education, and Welfare, a petition proposing the issuance of a regulation establishing a tolerance for a pesticide chemical which constitutes, or is an ingredient of, such economic poison, or exempting the pesticide chemical from the requirement of a tolerance. The petition shall contain data showing—

(A) the name, chemical identity, and composition of the pesticide chemical;

(B) the amount, frequency, and time of application of the pesticide chemical;

(C) full reports of investigations made with respect to the safety of the pesticide chemical;

(D) the results of tests on the amount of residue remaining, including a description of the analytical methods used;

(E) practicable methods for removing residue which exceeds any proposed tolerance;

(F) proposed tolerances for the pesticide chemical if tolerances are proposed; and

(G) reasonable grounds in support of the petition.

Samples of the pesticide chemical shall be furnished to the Secretary upon request. Notice of the filing of such petition shall be published in general terms by the Secretary within thirty days after filing. Such notice shall include the analytical methods available for the determination of the residue of the pesticide chemical for which a tolerance or exemption is proposed.

(2) Within ninety days after a certification of usefulness by the Secretary of Agriculture under subsection (l) of this section with respect to the pesticide chemical named in the petition, the Secretary of Health, Education, and Welfare shall, after giving due consideration to the data submitted in the petition or otherwise before him, by order make public a regulation—

(A) establishing a tolerance for the pesticide chemical named in the petition for the purposes for which it is so certified as useful, or

(B) exempting the pesticide chemical from the necessity of a tolerance for such purposes,

unless within such ninety-day period the person filing the petition requests that the petition be referred to an advisory committee or the Secretary within such period otherwise deems such referral necessary, in either of which events the provisions of paragraph (3) of this subsection shall apply in lieu hereof.

(3) In the event that the person filing the petition requests, within ninety days after a certification of usefulness by the Secretary of Agriculture under subsection (l) of this section with respect to the pesticide chemical named in the petition, that the petition be referred to an advisory committee, or in the event the Secretary of Health, Education, and Welfare within such period otherwise deems such referral necessary, the Secretary of Health, Education, and Welfare shall forthwith submit the petition and other data before him to an advisory committee to be appointed in accordance with subsection (g) of this section. As soon as practicable after such referral, but not later than sixty days thereafter, unless extended as hereinafter provided, the committee shall, after independent study of the data submitted to it by the Secretary and other data before it, certify to the Secretary a report and recommendations on the proposal in the petition to the Secretary, together with all underlying data and a statement of the reasons or basis for the recommendations. The sixty-day period provided for herein may be extended by the advisory committee for an additional thirty days if the advisory committee deems this necessary. Within thirty days after such certification, the Secretary shall, after giving due consideration to all data then before him, including such report, recommendations, underlying data, and statement, by order make public a regulation—

(A) establishing a tolerance for the pesticide chemical named in the petition for the purposes for which it is so certified as useful; or

(B) exempting the pesticide chemical from the necessity of a tolerance for such purposes.

(4) The regulations published under paragraph (2) or (3) of this subsection will be effective upon publication.

(5) Within thirty days after publication, any person adversely affected by a regulation published pursuant to paragraph (2) or (3) of this subsection, or pursuant to subsection (e) of this section, may file objections thereto with the Secretary, specifying with particularity the provisions of the regulation deemed objectionable, stating reasonable grounds therefor, and requesting a public hearing upon such objections. A copy of the objections filed by a person other than the petitioner shall be served on the petitioner, if the regulation was issued pursuant to a petition. The petitioner shall have two weeks to make a written reply to the objections. The Secretary shall thereupon, after due notice, hold such public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. Any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee shall be made a part of the record of the hearing, if relevant and material, subject to the provisions of section 1006 (c) of Title 5. The National Academy of Sciences shall designate a member of the advisory committee to appear and testify at any such hearing with respect to the report and recommendations of such committee upon request of the Secretary, the petitioner, or the officer conducting the hearing: *Provided*, That this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing. As soon as practicable after completion of the hearing, the Secretary shall act upon such objections and by order make public a regulation. Such regulation shall be based only on substantial evidence of record at such hearing, including any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee, and shall set forth detailed findings of fact upon which the regulation is based. No such order shall take effect prior to the ninetieth day after its publication, unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

(e) Regulations pursuant to Secretary's proposals.

The Secretary may at any time, upon his own initiative or upon the request of any interested person, propose the issuance of a regulation establishing a tolerance for a pesticide chemical or exempting it from the necessity of a tolerance. Thirty days after publication of such a proposal, the Secretary may by order publish a regulation based upon the proposal which shall become effective upon publication unless within such thirty-day period a person who has registered, or who has submitted an application for the registration of, an economic poison under the Federal Insecticide, Fungicide, and Rodenticide Act containing the pesticide chemical named in the proposal, requests that the proposal be referred to an advisory committee. In the event of such a request, the Secretary shall forthwith submit the proposal and other relevant data before him to an advisory committee to be appointed in accordance with subsection (g) of this section. As soon as practicable after such referral, but not later than sixty days thereafter, unless extended as hereinafter provided, the committee shall, after independent study of the data submitted to it by the Secretary and other data before it, certify to the Secretary a report and recommendations on the proposal together with all underlying data and a statement of the reasons or basis for the recommendations. The sixty-day period provided for herein may be extended by the advisory committee for an additional thirty days if the advisory committee deems this necessary. Within thirty days after such certification, the Secretary may, after giving due consideration to all data before him, including such report, recommendations, underlying data and statement, by order publish a regulation establishing a tolerance for the pesticide chemical named in the proposal or exempting it from the necessity of a tolerance which shall become effective upon publication. Regulations issued under this subsection shall upon publication be subject to paragraph (5) of subsection (d) of this section.

(f) Data submitted as confidential.

All data submitted to the Secretary or to an advisory committee in support of a petition under this section shall be considered confidential by the Secretary and by such advisory committee until publication of a regulation under paragraph (2) or (3) of subsection (d) of this section. Until such publication, such data shall not be revealed to any person other than those authorized by the Secretary or by an advisory committee in the carrying out of their official duties under this section.

(g) Advisory committees; appointment; composition; compensation; clerical assistance.

Whenever the referral of a petition or proposal to an advisory committee is requested under this section, or the Secretary otherwise deems such referral necessary the Secretary shall forthwith appoint a committee of competent experts to review the petition or proposal and to make a report and recommendations thereon. Each such advisory committee shall be composed of experts, qualified in the subject matter of the petition and of adequately diversified professional background selected by the National Academy of Sciences and shall include one or more representatives from land-grant colleges. The size of the committee shall be determined by the Secretary. Members of an advisory committee shall receive as compensation for their services a reasonable per diem, which the Secretary shall by rules and regulations prescribe, for time actually spent in the work of the committee, and shall in addition be reimbursed for their necessary traveling and subsistence expenses while so serving away from their places of residence. The members shall not be subject to any other provisions of law regarding the appointment and compensation of employees of the United States. The Secretary shall furnish the committee with adequate clerical and other assistance, and shall by rules and regulations prescribe the procedure to be followed by the committee.

(h) Right of consultation.

A person who has filed a petition or who has requested the referral of a proposal to an advisory

committee in accordance with the provisions of this section, as well as representatives of the Department of Health, Education, and Welfare, shall have the right to consult with any advisory committee provided for in subsection (g) of this section in connection with the petition or proposal.

(i) Judicial review.

(1) In a case of actual controversy as to the validity of any order under subsections (d) (5), (e), or (*l*) of this section any person who will be adversely affected by such order may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein such person resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a petition praying that the order be set aside in whole or in part.

(2) In the case of a petition with respect to an order under subsection (d) (5) or (e) of this section, a copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall file in the court the record of the proceedings on which he based his order, as provided in section 2112 of Title 28. Upon the filing of such petition, the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The findings of the Secretary with respect to questions of fact shall be sustained if supported by substantial evidence when considered on the record as a whole, including any report and recommendation of an advisory committee.

(3) In the case of a petition with respect to an order under subsection (*l*) of this section, a copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary of Agriculture, or any officer designated by him for that purpose, and thereupon the Secretary shall file in the court the record of the proceedings on which he based his order, as provided in section 2112 of Title 28. Upon the filing of such petition, the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The findings of the Secretary with respect to questions of fact shall be sustained if supported by substantial evidence when considered on the record as a whole.

(4) If application is made to the court for leave to adduce additional evidence, the court may order such additional evidence to be taken before the Secretary of Health, Education, and Welfare or the Secretary of Agriculture, as the case may be, and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper, if such evidence is material and there were reasonable grounds for failure to adduce such evidence in the proceedings below. The Secretary of Health, Education, and Welfare or the Secretary of Agriculture, as the case may be, may modify his findings as to the facts and order by reason of the additional evidence so taken, and shall file with the court such modified findings and order.

(5) The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of Title 28. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order. The courts shall advance on the docket and expedite the disposition of all causes filed therein pursuant to this section.

(j) Temporary tolerances.

The Secretary may, upon the request of any person who has obtained an experimental permit for a pesticide chemical under the Federal Insecticide, Fungicide, and Rodenticide Act or upon his own initiative, establish a temporary tolerance for the pesticide chemical for the uses covered by the permit whenever in his judgment such action is deemed necessary to protect the public health, or may temporarily exempt such pesticide chemical from a tolerance. In establishing such a tolerance, the Secretary shall give due regard to the necessity for experimental work in developing an adequate, wholesome, and economical food supply and to the limited hazard to the public health involved in such work when conducted in accordance with applicable regulations under the Federal Insecticide, Fungicide, and Rodenticide Act.

(k) Regulations based on public hearings before January 1, 1953.

Regulations affecting pesticide chemicals in or on raw agricultural commodities which are promulgated under the authority of section 346 (a) of this title upon the basis of public hearings instituted before January 1, 1953, in accordance with section 371 (a) of this title, shall be deemed to be regulations under this section and shall be subject to amendment or repeal as provided in subsection (m) of this section.

(*l*) Functions of Secretary of Agriculture; certifications; hearing; time limitation; opinion; regulations.

The Secretary of Agriculture, upon request of any person who has registered, or who has submitted an application for the registration of, an economic poison under the Federal Insecticide, Fungicide, and Rodenticide Act, and whose request is accompanied by a copy of a petition filed by such person under subsection (d) (1) of this section with respect to a pesticide chemical which constitutes, or is an ingredient of, such economic poison, shall, within thirty days or within sixty days if upon notice prior to the termination of such thirty days the Secretary deems it necessary to postpone action for such period, on the basis of data before him, either—

(1) certify to the Secretary of Health, Education, and Welfare that such pesticide chemical is useful for the purpose for which a tolerance or exemption is sought; or

(2) notify the person requesting the certification of his proposal to certify that the pesticide chemical does not appear to be useful for the purpose for which a tolerance or exemption is sought, or appears to be useful for only some of the purposes for which a tolerance or exemption is sought.

In the event that the Secretary of Agriculture takes the action described in clause (2) of the preceding

sentence, the person requesting the certification, within one week after receiving the proposed certification, may either (A) request the Secretary of Agriculture to certify to the Secretary of Health, Education, and Welfare on the basis of the proposed certification; (B) request a hearing on the proposed certification or the parts thereof objected to; or (C) request both such certification and such hearing. If no such action is taken, the Secretary may by order make the certification as proposed. In the event that the action described in clause (A) or (C) is taken, the Secretary shall by order make the certification as proposed with respect to such parts thereof as are requested. It[1] the event a hearing is requested, the Secretary of Agriculture shall provide opportunity for a prompt hearing. The certification of the Secretary of Agriculture as the result of such hearing shall be made by order and shall be based only on substantial evidence of record at the hearing and shall set forth detailed findings of fact. In no event shall the time elapsing between the making of a request for a certification under this subsection and final certification by the Secretary of Agriculture exceed one hundred and sixty days. The Secretary shall submit to the Secretary of Health, Education, and Welfare with any certification of usefulness under this subsection an opinion, based on the data before him, whether the tolerance or exemption proposed by the petitioner reasonably reflects the amount of residue likely to result when the pesticide chemical is used in the manner proposed for the purpose for which the certification is made. The Secretary of Agriculture, after due notice and opportunity for public hearing, is authorized to promulgate rules and regulations for carrying out the provisions of this subsection.

(m) Amendment of regulations.

The Secretary of Health, Education, and Welfare shall prescribe by regulations the procedure by which regulations under this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of regulations establishing tolerances, including the appointment of advisory committees and the procedure for referring petitions to such committees.

(n) Guaranties.

The provisions of section 333 (c) of this title with respect to the furnishing of guaranties shall be applicable to raw agricultural commodities covered by this section.

(o) Payment of fees; services or functions as conditioned on; waiver or refund of fees.

The Secretary of Health, Education, and Welfare shall by regulation require the payment of such fees as will in the aggregate, in the judgment of the Secretary, be sufficient over a reasonable term to provide, equip, and maintain an adequate service for the performance of the Secretary's functions under this section. Under such regulations, the performance of the Secretary's services or other functions pursuant to this section, including any one or more of the following, may be conditioned upon the payment of such fees: (1) The acceptance of filing of a petition submitted under subsection (d) of this section; (2) the promulgation of a regulation establishing a tolerance, or an exemption from the necessity of a tolerance, under this section, or the amendment or repeal of such a regulation; (3) the referral of a petition or proposal under this section to an advisory committee; (4) the acceptance for filing of objections under subsection (d) (5) of this section; or (5) the certification and filing in court of a transcript of the proceedings and the record under subsection (i) (2) of this section. Such regulations may further provide for waiver or refund of fees in whole or in part when in the judgment of the Secretary such waiver or refund is equitable and not contrary to the purposes of this subsection. (June 25, 1938, ch. 675, § 408, as added July 22, 1954, ch. 559, § 3, 68 Stat. 511, and amended Aug. 28, 1958, Pub. L. 85–791, § 20, 72 Stat. 947.)

[1] So in original. Probably should read "In."

REFERENCES IN TEXT

The Federal Insecticide, Fungicide, and Rodenticide Act, referred to in subsecs. (d) (1), (e), (j) and (l), is classified to sections 135—135k of Title 7, Agriculture.

AMENDMENTS

1958—Subsec. (i) (2) amended by Pub. L. 85–791, § 20 (a), which, in first sentence, substituted "transmitted by the clerk of the court to the Secretary, or" for "served upon the Secretary, or upon", substituted "file in the court the record of the proceedings" for "certify and file in the court a transcript of the proceedings and the record", and inserted "as provided in section 2112 of Title 28", and which, in second sentence, substituted "the filing of such petition" for "such filing".

Subsec. (i) (3) amended by Pub. L. 85–791, § 20 (b), which, in first sentence, substituted "transmitted by the clerk of the court to the Secretary of Agriculture, or" for "served upon the Secretary of Agriculture, or upon", substituted "file in the court the record of the proceedings" for "certify and file in the court a transcript of the proceedings and the record", and inserted "as provided in section 2112 of Title 28", and, in second sentence, substituted "the filing of such petition" for "such filing".

EFFECTIVE DATE

Effective date of section, see note under section 342 of this title.

§ 346b. Same; appropriations.

There are authorized to be appropriated, out of any moneys in the Treasury not otherwise appropriated, such sums as may be necessary for the purpose and administration of sections 321 (q), (r), 342 (a) (2), and 346a of this title. (July 22, 1954, ch. 559, § 4, 68 Stat. 517.)

§ 347. Intrastate sales of colored oleomargarine.

(a) Law governing.

Colored oleomargarine or colored margarine which is sold in the same State or Territory in which it is produced shall be subject in the same manner and to the same extent to the provisions of this chapter as if it had been introduced in interstate commerce.

(b) Labeling and packaging requirements.

No person shall sell, or offer for sale, colored oleomargarine or colored margarine unless—

(1) such oleomargarine or margarine is packaged,

(2) the net weight of the contents of any package sold in a retail establishment is one pound or less,

(3) there appears on the label of the package (A) the word "oleomargarine" or "margarine" in type or lettering at least as large as any other type or lettering on such label, and (B) a full and accurate statement of all the ingredients contained in such oleomargarine or margarine, and

(4) each part of the contents of the package is contained in a wrapper which bears the word "oleomargarine" or "margarine" in type or lettering not smaller than 20-point type.

The requirements of this subsection shall be in addition to and not in lieu of any of the other requirements of this chapter.

(c) Sales in public eating places.

No person shall possess in a form ready for serving colored oleomargarine or colored margarine at a public eating place unless a notice that oleomargarine or margarine is served is displayed prominently and conspicuously in such place and in such manner as to render it likely to be read and understood by the ordinary individual being served in such eating place or is printed or is otherwise set forth on the menu in type or lettering not smaller than that normally used to designate the serving of other food items. No person shall serve colored oleomargarine or colored margarine at a public eating place, whether or not any charge is made therefor, unless (1) each separate serving bears or is accompanied by labeling identifying it as oleomargarine or margarine, or (2) each separate serving thereof is triangular in shape.

(d) Same; exemption from labeling requirements.

Colored oleomargarine or colored margarine when served with meals at a public eating place shall at the time of such service be exempt from the labeling requirements of section 343 of this title (except subsection (a) and (f) of section 343 of this title) if it complies with the requirements of subsection (b) of this section.

(e) Color content of oleomargarine.

For the purpose of this section colored oleomargarine or colored margarine is oleomargarine or margarine having a tint or shade containing more than one and six-tenths degrees of yellow, or of yellow and red collectively, but with an excess of yellow over red, measured in terms of Lovibond tintometer scale or its equivalent. (June 25, 1938, ch. 675, § 407, as added Mar. 16, 1950, ch. 61, § 3 (c), 64 Stat. 20.)

EFFECTIVE DATE

Section 7 of act Mar. 16, 1950, provided that: "This Act [sections 331 (m), 342 (e), and 347—347b of this title and sections 45 (*l*) and 55 (a), (f) of Title 15] shall become effective on July 1, 1950."

TRANSFER OF APPROPRIATIONS

Section 5 of act Mar. 16, 1950, provided that: "So much of the unexpended balances of appropriations, allocations, or other funds (including funds available for the fiscal year ending June 30, 1950) for the use of the Bureau of Internal Revenue of the Treasury Department in the exercise of functions under the Oleomargarine Tax Act (26 U. S. C., § 2300, subchapter A) [now section 4591 et seq. of Title 26], as the Director of the Bureau of the Budget may determine, shall be transferred to the Federal Security Agency (Food and Drug Administration) for use in the enforcement of this Act [sections 331 (m), 342 (e), and 347—347b of this title and sections 45 (*l*) and 55 (a), (f) of Title 15, Commerce and Trade.]"

§ 347a. Congressional declaration of policy regarding oleomargarine sales.

The Congress finds and declares that the sale, or the serving in public eating places, of colored oleomargarine or colored margarine without clear identification as such or which is otherwise adulterated or misbranded within the meaning of this chapter depresses the market in interstate commerce for butter and for oleomargarine or margarine clearly identified and neither adulterated nor misbranded, and constitutes a burden on interstate commerce in such articles. Such burden exists, irrespective of whether such oleomargarine or margarine originates from an interstate source or from the State in which it is sold. (Mar. 16, 1950, ch. 61, § 3 (a), 64 Stat. 20.)

CODIFICATION

Section was not enacted as a part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

EFFECTIVE DATE

Section as effective July 1, 1950, see note set out under section 347 of this title.

§ 347b. Contravention of State laws.

Nothing in sections 331 (m), 342 (e), and 347—347b of this title, and sections 45 (*l*) and 55 (a), (f) of Title 15 shall be construed as authorizing the possession, sale, or serving of colored oleomargarine or colored margarine in any State or Territory in contravention of the laws of such State or Territory. (Mar. 16, 1950, ch. 61, § 6, 64 Stat. 22.)

CODIFICATION

Section was not enacted as a part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

EFFECTIVE DATE

Section as effective July 1, 1950, see note set out under section 347 of this title.

§ 348. Food additives.

(a) Unsafe food additives; exception for conformity with exemption or regulation.

A food additive shall, with respect to any particular use or intended use of such additives, be deemed to be unsafe for the purposes of the application of clause (2) (C) of section 342 (a) of this title, unless—

(1) it and its use or intended use conform to the terms of an exemption which is in effect pursuant to subsection (i) of this section; or

(2) there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used.

While such a regulation relating to a food additive is in effect, a food shall not, by reason of bearing or containing such an additive in accordance with the regulation, be considered adulterated within the meaning of clause (1) of section 342 (a) of this title.

(b) Petition for regulation prescribing conditions of safe use; contents; description of production methods and controls; samples; notice of regulation.

(1) Any person may, with respect to any intended use of a food additive, file with the Secretary a petition proposing the issuance of a regulation prescribing the conditions under which such additive may be safely used.

(2) Such petition shall, in addition to any explanatory or supporting data, contain—

(A) the name and all pertinent information concerning such food additive, including, where available, its chemical identity and composition;

(B) a statement of the conditions of the proposed use of such additive, including all directions, recommendations, and suggestions proposed for the use of such additive, and including specimens of its proposed labeling;

(C) all relevant data bearing on the physical or other technical effect such additive is intended to produce, and the quantity of such additive required to produce such effect;

(D) a description of practicable methods for determining the quantity of such additive in or on food, and any substance formed in or on food, because of its use; and

(E) full reports of investigations made with respect te the safety for use of such additive, including full information as to the methods and controls used in conducting such investigations.

(3) Upon request of the Secretary, the petitioner shall furnish (or, if the petitioner is not the manufacturer of such additive, the petitioner shall have the manufacturer of such additive furnish, without disclosure to the petitioner) a full description of the methods used in, and the facilities and controls used for, the production of such additive.

(4) Upon request of the Secretary, the petitioner shall furnish samples of the food additive involved, or articles used as components thereof, and of the food in or on which the additive is proposed to be used.

(5) Notice of the regulation proposed by the petitioner shall be published in general terms by the Secretary within thirty days after filing.

(c) Approval or denial of petition; time for issuance of orders; evaluation of data; factors.

(1) The Secretary shall—

(A) by order establish a regulation (whether or not in accord with that proposed by the petitioner) prescribing, with respect to one or more proposed uses of the food additive involved, the conditions under which such additive may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or in which such additive may be used, the maximum quantity which may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use), and shall notify the petitioner of such order and the reasons for such action; or

(B) by order deny the petition, and shall notify the petitioner of such order and of the reasons for such action.

(2) The order required by paragraph (1) (A) or (B) of this subsection shall be issued within ninety days after the date of filing of the petition, except that the Secretary may (prior to such ninetieth day), by written notice to the petitioner, extend such ninety-day period to such time (not more than one hundred and eighty days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigato the petition.

(3) No such regulation shall issue if a fair evaluation of the data before the Secretary—

(A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe: *Provided*, That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal; or

(B) shows that the proposed use of the additive would promote deception of the consumer in violation of this chapter or would otherwise result in adulteration or in misbranding of food within the meaning of this chapter.

(4) If, in the judgment of the Secretary, based upon a fair evaluation of the data before him, a tolerance limitation is required in order to assure that the proposed use of an additive will be safe, the Secretary—

(A) shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the physical or other technical effect for which such additive is intended; and

(B) shall not establish a regulation for such proposed use if he finds upon a fair evaluation of the data before him that such data do not establish that such use would accomplish the intended physical or other technical effect.

(5) In determining, for the purposes of this section, whether a proposed use of a food additive is safe, the Secretary shall consider among other relevant factors—

(A) the probable consumption of the additive and of any substance formed in or on food because of the use of the additive;

(B) the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet; and

(C) safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as appropriate for the use of animal experimentation data.

(d) Regulation issued on Secretary's initiative.

The Secretary may at any time, upon his own initiative, propose the issuance of a regulation prescribing, with respect to any particular use of a food additive, the conditions under which such additive may be safely used, and the reasons therefor. After the thirtieth day following publication of such a proposal, the Secretary may by order establish a regulation based upon the proposal.

(e) Publication and effective date of orders.

Any order, including any regulation established by such order, issued under subsection (c) or (d) of this section, shall be published and shall be effective upon publication, but the Secretary may

stay such effectiveness if, after issuance of such order, a hearing is sought with respect to such order pursuant to subsection (f) of this section.

(f) Objections and public hearing; basis and contents of order; statement.

(1) Within thirty days after publication of an order made pursuant to subsection (c) or (d) of this section, any person adversely affected by such an order may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds therefor, and requesting a public hearing upon such objections. The Secretary shall, after due notice, as promptly as possible hold such public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public.

(2) Such order shall be based upon a fair evaluation of the entire record at such hearing, and shall include a statement setting forth in detail the findings and conclusions upon which the order is based.

(3) The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication, unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

(g) Judicial review.

(1) In a case of actual controversy as to the validity of any order isued under subsection (f) of this section, including any order thereunder with respect to amendment or repeal of a regulation issued under this section, any person who will be adversely affected by such order may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein such person resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a petition praying that the order be set aside in whole or in part.

(2) A copy of such petition shall be forthwith served upon the Secretary, or upon any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court a transcript of the proceedings and the record on which he based his order. Upon such filing, the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The findings of the Secretary with respect to questions of fact shall be sustained if based upon a fair evaluation of the entire record at such hearing. The court shall advance on the docket and expedite the disposition of all causes filed therein pursuant to this section.

(3) The court, on such judicial review, shall not sustain the order of the Secretary if he failed to comply with any requirement imposed on him by subsection (f) (2) of this section.

(4) If application is made to the court for leave to adduce additional evidence, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper, if such evidence is material and there were reasonable grounds for failure to adduce such evidence in the proceedings below. The Secretary may modify his findings as to the facts and order by reason of the additional evidence so taken, and shall file with the court such modified findings and order.

(5) The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of Title 28. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order.

(h) Amendment or repeal of regulations.

The Secretary shall by regulation prescribe the procedure by which regulations under the foregoing provisions of this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of such regulations.

(i) Exemptions for investigational use.

Without regard to subsections (b) to (h), inclusive, of this section, the Secretary shall by regulation provide for exempting from the requirements of this section any food additive, and any food bearing or containing such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health. (June 25, 1938, ch. 675, § 409, as added Sept. 6, 1958, Pub. L. 85-929, § 4, 72 Stat. 1785.)

EFFECTIVE DATE

Section as effective Sept. 6, 1958, see section 6 (a) of Pub. L. 85-929, set out as note under section 342 of this title.

SUBCHAPTER V.—DRUGS AND DEVICES

§ 351. Adulterated drugs and devices.

A drug or device shall be deemed to be adulterated—

(a) Poisonous, insanitary, etc., ingredients.

(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (3) if it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if it is a drug and it bears or contains, for purposes of coloring only, a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 354 of this title.

(b) Strength, quality, or purity differing from official compendium.

If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such

compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, except that whenever tests or methods of assay have not been prescribed in such compendium, or such tests or methods of assay as are prescribed are, in the judgment of the Secretary, insufficient for the making of such determination, the Secretary shall bring such fact to the attention of the appropriate body charged with the revision of such compendium, and if such body fails within a reasonable time to prescribe tests or methods of assay which, in the judgment of the Secretary, are sufficient for purposes of this subsection, then the Secretary shall promulgate regulations prescribing appropriate tests or methods of assay in accordance with which such determination as to strength, quality, or purity shall be made. No drug defined in an official compendium shall be deemed to be adulterated under this subsection because it differs from the standard of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such standard is plainly stated on its label. Whenever a drug is recognized in both the United States Pharmacopœia and the Homœopathic Pharmacopœia of the United States it shall be subject to the requirements of the United States Pharmacopœia unless it is labeled and offered for sale as a homœopathic drug, in which case it shall be subject to the provisions of the Homœopathic Pharmacopœia of the United States and not to those of the United States Pharmacopœia.

(c) Misrepresentation of strength, etc., where drug is unrecognized in compendium.

If it is not subject to the provisions of subsection (b) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

(d) Mixture with or substitution of another substance.

If it is a drug and any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor. (June 25, 1938, ch. 675, § 501, 52 Stat. 1049; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F. R. 2422, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F. R. 2053, 67 Stat. 631.)

EFFECTIVE DATE

Section 902 (a) of act June 25, 1938, provided that this section should take effect twelve months after June 25, 1938. Act June 23, 1939, ch. 242, § 1, 53 Stat. 853, provided that the effective date of subsection (a) (4) should be postponed until January 1, 1940.

TRANSFER OF FUNCTIONS

All functions of the Federal Security Administrator were transferred to the Secretary of Health, Education, and Welfare and all agencies of the Federal Security Agency were transferred to the Department of Health, Education, and Welfare by section 5 of 1953 Reorg. Plan No. 1, set out as a note under section 623 of Title 5, Executive Departments and Government Officers and Employees. The Federal Security Agency and the office of Administrator were abolished by section 8 of 1953 Reorg. Plan No. 1.

See, also, note under section 321 of this title.

§ 352. Misbranded drugs and devices.

A drug or device shall be deemed to be misbranded—

(a) False or misleading label.

If its labeling is false or misleading in any particular.

(b) Package form; contents of label.

If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (2) of this subsection reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(c) Prominence of information on label.

If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) Habit-forming substances.

If it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha eucaine, barbituric acid, betacucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote, or sulphonmethane; or any chemical derivative of such substance, which derivative has been by the Secretary, after investigation, found to be, and by regulations designated as, habit forming; unless its label bears the name and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

(e) Designation of drug by name not in compendium.

If it is a drug and is not designated solely by a name recognized in an official compendium unless its label bears (1) the common or usual name of the drug, if such there be; and (2), in case it is fabricated from two or more ingredients, the common or usual name of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including, whether active or not, the name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein: *Provided*, That to the extent that compliance with the requirements of clause (2) of this subsection is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

(f) Directions for use and warnings on label.

Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: *Provided*, That where any requirement of clause (1) of this subsection, as applied to any drug or device, is not necessary for

the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

(g) Representation as recognized drug; packing and labeling.

If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein: *Provided*, That the method of packing may be modified with the consent of the Secretary. Whenever a drug is recognized in both the United States Pharmacopœia and the Homœopathic Pharmacopœia of the United States, it shall be subject to the requirements of the United States Pharmacopœia with respect to packaging and labeling unless it is labeled and offered for sale as a homœopathic drug, in which case it shall be subject to the provisions of the Homœopathic Pharmacopœia of the United States, and not to those of the United States Pharmacopœia.

(h) Deteriorative drugs; packing and labeling.

If it has been found by the Secretary to be a drug liable to deterioration, unless it is packaged in such form and manner, and its label bears a statement of such precautions, as the Secretary shall by regulations require as necessary for the protection of the public health. No such regulation shall be established for any drug recognized in an official compendium until the Secretary shall have informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body shall have failed within a reasonable time to prescribe such requirements.

(i) Drug; misleading container; imitation; offer for sale under another name.

(1) If it is a drug and its container is so made, formed, or filled as to be misleading; or (2) if it is an imitation of another drug; or (3) if it is offered for sale under the name of another drug.

(j) Health-endangering when used as prescribed.

If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

(k) Insulin not properly certified.

If it is, or purports to be, or is represented as a drug composed wholly or partly of insulin, unless (1) it is from a batch with respect to which a certificate or release has been issued pursuant to section 356, and (2) such certificate or release is in effect with respect to such drug.

(*l*) Penicillin improperly certified.

If it is, or purports to be, or is represented as a drug composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin, or any derivative thereof, unless (1) it is from a batch with respect to which a certificate or release has been issued pursuant to section 357 of this title, and (2) such certificate or release is in effect with respect to such drug: *Provided*, That this subsection shall not apply to any drug or class of drugs exempted by regulations promulgated under section 357 (c) or (d) of this title. (June 25, 1938, ch. 675, § 502, 52 Stat. 1050; June 23, 1939, ch. 242, § 3, 53 Stat. 854; 1940 Reorg. Plan No. IV, §§ 12, 13, eff. June 30, 1940, 5 F. R. 2422, 54 Stat. 1237; Dec. 22, 1941, ch. 613, § 2, 55 Stat. 851; July 6, 1945, ch. 281, § 2, 59 Stat. 463; Mar. 10, 1947, ch. 16, § 2, 61 Stat. 11; July 13, 1949, ch. 305, § 1, 63 Stat. 409; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F. R. 2053, 67 Stat. 631; Aug. 5, 1953, ch. 334, § 1, 67 Stat. 389.)

AMENDMENTS

1953—Subsec. (*l*) amended by act Aug. 5, 1953, to substitute "chlortetracycline" for "aureomycin".

1949—Subsec. (*l*) amended by act July 13, 1949, which inserted ", aureomycin, chloramphenicol, or bacitracin" following "streptomycin".

1947—Subsec. (*l*) amended by act Mar. 10, 1947, which inserted "or streptomycin" following "penicillin".

1945—Subsec. (*l*) added by act July 6, 1945.

1941—Subsec. (k) added by act Dec. 22, 1941.

EFFECTIVE DATE

Section 902 (a) of act June 25, 1938, provided that this section should take effect twelve months after June 25, 1938, except subsection (j), which was to take effect on June 25, 1938. Act June 23, 1939, §§ 1 (a), 2 (c), provided that the effective date of subsections (b) and (d)—(h), should be postponed until January 1, 1940, except insofar as subsections (d) and (e) related to any substance named in former section 10 of this title under the heading "Drugs" and except insofar as paragraphs (b) and (d)—(h) related to drugs to which section 355 of this title applies.

TRANSFER OF FUNCTIONS

All functions of the Federal Security Administrator were transferred to the Secretary of Health, Education, and Welfare and all agencies of the Federal Security Agency were transferred to the Department of Health, Education, and Welfare by section 5 of 1953 Reorg. Plan No. 1, set out as a note under section 623 of Title 5, Executive Departments and Government Officers and Employees. The Federal Security Agency and the office of Administrator were abolished by section 8 of 1953 Reorg. Plan No. 1.

See, also, note under section 321 of this title.

§ 353. Exemptions in case of drugs and devices.

(a) Regulations for goods to be processed, labeled, or repacked elsewhere.

The Secretary is directed to promulgate regulations exempting from any labeling or packaging requirement of this chapter drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs and devices are not adulterated or misbranded under the provisions of this chapter upon removal from such processing, labeling, or repacking establishment.

(b) Prescription by physician; exemption from labeling and prescription requirements; misbranded drugs; compliance with narcotic and marihuana laws.

(1) A drug intended for use by man which—

(A) is a habit-forming drug to which section 352 (d) of this title applies; or

(B) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(C) is limited by an effective application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug,

shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

(2) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of section 352 of this title, except subsections (a), (i) (2) and (3), (k), and (*l*) of said section, and the packaging requirements of subsections (g) and (h) of said section, if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of paragraph (1) of this subsection.

(3) The Secretary may by regulation remove drugs subject to sections 352 (d) and 355 of this title from the requirements of paragraph (1) of this subsection when such requirements are not necessary for the protection of the public health.

(4) A drug which is subject to paragraph (1) of this subsection shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement "Caution: Federal law prohibits dispensing without prescription". A drug to which paragraph (1) of this subsection does not apply shall be deemed to be misbranded if at any time prior to dispensing its label bears the caution statement quoted in the preceding sentence.

(5) Nothing in this subsection shall be construed to relieve any person from any requirement prescribed by or under authority of law with respect to drugs now included or which may hereafter be included within the classifications stated in section 3220 of Title 26, or to marihuana as defined in section 3238 (b) of Title 26. (June 25, 1938, ch. 675, § 503, 52 Stat. 1051; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F. R. 2422, 54 Stat. 1237; Oct. 26, 1951, ch. 578, § 1, 65 Stat. 648; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F. R. 2053, 67 Stat. 631.)

REFERENCES IN TEXT

Sections 3220 and 3238 (b) of Title 26, referred to in subsec. (b) (5) of this section, which were references to sections 3220 and 3238 (b) of the Internal Revenue Code of 1939, were repealed by section 7851 of Title 26, I. R. C. 1954, and are now covered by sections 4721, 4761, 6001, 6151 (a), and 7701 (a) of said Title 26. For provision deeming a reference in other laws to a provision of I. R. C. 1939, also as a reference to corresponding provision of I. R. C. 1954, see section 7852 (b) of said Title 26.

AMENDMENTS

1951—Subsec. (b) amended generally by act Oct. 26, 1951, to protect the public from abuses in the sale of potent prescription drugs, and to relieve retail pharmacists and the public from unnecessary restrictions on the dispensation of drugs that are safe to use without supervision of a doctor.

EFFECTIVE DATE OF 1951 AMENDMENT

Section 3 of act Oct. 26, 1951, provided that the amendment of this section should take effect six months after Oct. 26, 1951.

EFFECTIVE DATE

Section 902 (a) of act June 25, 1938, provided that this section should take effect twelve months after June 25, 1938.

TRANSFER OF FUNCTIONS

All functions of the Federal Security Administrator were transferred to the Secretary of Health, Education, and Welfare and all agencies of the Federal Security Agency were transferred to the Department of Health, Education, and Welfare by section 5 of 1953 Reorg. Plan No. 1, set out as a note under section 623 of Title 5, Executive Departments and Government Officers and Employees. The Federal Security Agency and the office of Administrator were abolished by section 8 of 1953 Reorg. Plan No. 1.

See, also, note under section 321 of this title.

§ 354. Certification of coal-tar colors for drugs.

The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in drugs for purposes of coloring only and for the certification of batches of such colors, with or without harmless diluents. (June 25, 1938, ch. 675, § 504, 52 Stat. 1052; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F. R. 2422, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F. R. 2053, 67 Stat. 631.)

EFFECTIVE DATE

Section 902 (a) of act June 25, 1938, provided that this section should take effect twelve months after June 25, 1938.

TRANSFER OF FUNCTIONS

All functions of the Federal Security Administrator were transferred to the Secretary of Health, Education, and Welfare and all agencies of the Federal Security Agency were transferred to the Department of Health, Education, and Welfare by section 5 of 1953 Reorg. Plan No. 1, set out as a note under section 623 of Title 5, Executive Departments and Government Officers and Employees. The Federal Security Agency and the office of Administrator were abolished by section 8 of 1953 Reorg. Plan No. 1.

See, also, note under section 321 of this title.

§ 355. New drugs.

(a) Necessity of effective application.

No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an application filed pursuant to subsection (b) of this section is effective with respect to such drug.

(b) Filing application; contents.

Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a) of this section. Such person shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe for use; (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing

of such drug; (5) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (6) specimens of the labeling proposed to be used for such drug.

(c) Effective date of application.

An application provided for in subsection (b) of this section shall become effective on the sixtieth day after the filing thereof unless prior to such day the Secretary by notice to the applicant in writing postpones the effective date of the application to such time (not more than one hundred and eighty days after the filing thereof) as the Secretary deems necessary to enable him to study and investigate the application.

(d) Grounds for refusing application to become effective.

If the Secretary finds, after due notice to the applicant and giving him an opportunity for a hearing, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b) of this section, do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; or (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions, he shall, prior to the effective date of the application, issue an order refusing to permit the application to become effective.

(e) Suspension of effectiveness of application.

The effectiveness of an application with respect to any drug shall, after due notice and opportunity for hearing to the applicant, by order of the Secretary be suspended if the Secretary finds (1) that clinical experience, tests by new methods, or tests by methods not deemed reasonably applicable when such application became effective show that such drug is unsafe for use under the conditions of use upon the basis of which the application became effective, or (2) that the application contains any untrue statement of a material fact. The order shall state the findings upon which it is based.

(f) Revocation of order refusing effectiveness.

An order refusing to permit an application with respect to any drug to become effective shall be revoked whenever the Secretary finds that the facts so require.

(g) Service of orders.

Orders of the Secretary issued under this section shall be served (1) in person by any officer or employee of the Department designated by the Secretary or (2) by mailing the order by registered mail addressed to the applicant or respondent at his last-known address in the records of the Secretary.

(h) Appeal from order.

An appeal may be taken by the applicant from an order of the Secretary refusing to permit the application to become effective, or suspending the effectiveness of the application. Such appeal shall be taken by filing in the district court of the United States within any district wherein such applicant resides or has his principal place of business, or in the District Court of the United States for the District of Columbia, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside. A copy of such petition shall be forthwith served upon the Secretary, or upon any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court a transcript of the record upon which the order complained of was entered. Upon the filing of such transcript such court shall have exclusive jurisdiction to affirm or set aside such order. No objection to the order of the Secretary shall be considered by the court unless such objection shall have been urged before the Secretary or unless there were reasonable grounds for failure so to do. The finding of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive. If any person shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts by reason of the additional evidence so taken, and he shall file with the court such modified findings which, if supported by substantial evidence, shall be conclusive, and his recommendation, if any, for the setting aside of the original order. The judgment and decree of the court affirming or setting aside any such order of the Secretary shall be final, subject to review as provided in sections 225, 346, and 347 of Title 28, as amended, and in section 7, as amended, of the Act entitled "An Act to establish a Court of Appeals for the District of Columbia", approved February 9, 1893 (D. C. Code, title 18, sec. 26). The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of the Secretary's order.

(i) Exemption of drugs for research.

The Secretary shall promulgate regulations for exempting from the operation of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety of drugs. (June 25, 1938, ch. 675, § 505, 52 Stat. 1052; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F. R. 2422, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F. R. 2053, 67 Stat. 631.)

REFERENCES IN TEXT

Sections 225, 346, and 347 of Title 28, as amended, referred to in subsection (h), were repealed by act June 25, 1948, ch. 646, § 39, 62 Stat. 992, eff. Sept. 1, 1948, and are now covered by sections 1254 and 1291—1294 of Title 28, Judiciary and Judicial Procedure.

EFFECTIVE DATE

Section 902 (a) of act June 25, 1938, provided that this section should take effect June 25, 1938.

TRANSFER OF FUNCTIONS

All functions of the Federal Security Administrator were transferred to the Secretary of Health, Education, and Welfare and all agencies of the Federal Security Agency were transferred to the Department of Health, Education, and Welfare by section 5 of 1953 Reorg. Plan No. 1, set out as a note under section 623 of Title 5, Executive Departments and Government Officers and Employees. The Federal Security Agency and the office of Administrator were abolished by section 8 of 1953 Reorg. Plan No. 1.

See, also, note under section 321 of this title.

§ 356. Certification of drugs containing insulin.

(a) The Secretary of Health, Education, and Welfare, pursuant to regulations promulgated by him, shall provide for the certification of batches of drugs composed wholly or partly of insulin. A batch of any such drug shall be certified if such drug has such characteristics of identity and such batch has such characteristics of strength, quality, and purity, as the Secretary prescribes in such regulations as necessary to adequately insure safety and efficacy of use, but shall not otherwise be certified. Prior to the effective date of such regulations the Secretary, in lieu of certification, shall issue a release for any batch which, in his judgment, may be released without risk as to the safety and efficacy of its use. Such release shall prescribe the date of its expiration and other conditions under which it shall cease to be effective as to such batch and as to portions thereof.

(b) Regulations providing for such certification shall contain such provisions as are necessary to carry out the purposes of this section, including provisions prescribing (1) standards of identity and of strength, quality, and purity; (2) tests and methods of assay to determine compliance with such standards; (3) effective periods for certificates, and other conditions under which they shall cease to be effective as to certified batches and as to portions thereof; (4) administration and procedure; and (5) such fees, specified in such regulations, as are necessary to provide, equip, and maintain an adequate certification service. Such regulations shall prescribe no standard of identity or of strength, quality, or purity for any drug different from the standard of identity, strength, quality, or purity set forth for such drug in an official compendium.

(c) Such regulations, insofar as they prescribe tests or methods of assay to determine strength, quality, or purity of any drug, different from the tests or methods of assay set forth for such drug in an official compendium, shall be prescribed, after notice and opportunity for revision of such compendium, in the manner provided in the second sentence of section 351 (b) of this title. The provisions of subsections (e)—(g) of section 371 of this title shall be applicable to such portion of any regulation as prescribes any such different test or method, but shall not be applicable to any other portion of any such regulation. (June 25, 1938, ch. 675, § 506, as added Dec. 22, 1941, ch. 613, § 3, 55 Stat. 851, and amended 1953 Reorg. Plan. No. 1, § 5, eff. Apr. 11, 1953, 18 F. R. 2053, 67 Stat. 631.)

TRANSFER OF FUNCTIONS

All functions of the Federal Security Administrator were transferred to the Secretary of Health, Education, and Welfare and all agencies of the Federal Security Agency were transferred to the Department of Health, Education, and Welfare by section 5 of 1953 Reorg. Plan No. 1, set out as a note under section 623 of Title 5, Executive Departments and Government Officers and Employees. The Federal Security Agency and the office of Administrator were abolished by section 8 of 1953 Reorg. Plan No. 1.

REGULATIONS

Section 4 of act Dec. 22, 1941, provided: "Regulations initially prescribed under * * * (Title 21, § 356) shall be promulgated and made effective within forty-five days after the date of enactment of this Act."

§ 357. Certification of drugs containing penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin.

(a) Regulations prescribed by Secretary; release prior to certification.

The Secretary of Health, Education, and Welfare, pursuant to regulations promulgated by him, shall provide for the certification of batches of drugs composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin, or any derivative thereof. A batch of any such drug shall be certified if such drug has such characteristics of identity and such batch has such characteristics of strength, quality, and purity, as the Secretary prescribes in such regulations as necessary to adequately insure safety and efficacy of use, but shall not otherwise be certified. Prior to the effective date of such regulations the Secretary, in lieu of certification, shall issue a release for any batch which, in his judgment, may be released without risk as to the safety and efficacy of its use. Such release shall prescribe the date of its expiration and other conditions under which it shall cease to be effective as to such batch and as to portions thereof.

(b) Provisions of regulations.

Regulations providing for such certifications shall contain such provisions as are necessary to carry out the purposes of this section, including provisions prescribing (1) standards of identity and of strength, quality, and purity; (2) tests and methods of assay to determine compliance with such standards; (3) effective periods for certificates, and other conditions under which they shall cease to be effective as to certified batches and as to portions thereof; (4) administration and procedure; and (5) such fees, specified in such regulations, as are necessary to provide, equip, and maintain an adequate certification service. Such regulations shall prescribe only such tests and methods of assay as will provide for certification or rejection within the shortest time consistent with the purposes of this section.

(c) Exemption of drugs not involving safety and efficacy of use.

Whenever in the judgment of the Secretary, the requirements of this section and of section 352 (*l*) of this title with respect to any drug or class of drugs are not necessary to insure safety and efficacy of use, the Secretary shall promulgate regula-

tions exempting such drug or class of drugs from such requirements.

(d) Exemption of drugs stored, processed, and labeled at plants other than manufacturer, used in manufacture of other drugs or used for investigational purposes.

The Secretary shall promulgate regulations exempting from any requirement of this section and of section 352 (*l*) of this title, (1) drugs which are to be stored, processed, labeled, or repacked at establishments other than those where manufactured, on condition that such drugs comply with all such requirements upon removal from such establishments; (2) drugs which conform to applicable standards of identity, strength, quality, and purity prescribed by these regulations and are intended for use in manufacturing other drugs; and (3) drugs which are intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and efficacy of drugs.

(e) Determination of compliance with sections 351 (b) and 352 (g) of this title.

No drug which is subject to this section shall be deemed to be subject to any provision of section 355 of this title. Compliance of any drug subject to section 352 (*l*) of this title or this section with sections 351 (b) and 352 (g) of this title shall be determined by the application of the standards of strength, quality, and purity, the tests and methods of assay, and the requirements of packaging and labeling, respectively, prescribed by regulations promulgated under this section.

(f) Filing of petitions; contents; notice; answer; public hearing; orders.

Any interested person may file with the Secretary a petition proposing the issuance, amendment, or repeal of any regulation contemplated by this section. The petition shall set forth the proposal in general terms and shall state reasonable grounds therefor. The Secretary shall give public notice of the proposal and an opportunity for all interested persons to present their views thereon, orally or in writing, and as soon as practicable thereafter shall make public his action upon such proposal. At any time prior to the thirtieth day after such action is made public any interested person may file objections to such action, specifying with particularity the changes desired, stating reasonable grounds therefor, and requesting a public hearing upon such objections. The Secretary shall thereupon, after due notice, hold such public hearing. As soon as practicable after completion of the hearing, the Secretary shall by order make public his action on such objections. The Secretary shall base his order only on substantial evidence of record at the hearing and shall set forth as part of the order detailed findings of fact on which the order is based. The order shall be subject to the provisions of section 371 (f) and (g) of this title. (June 25, 1938, ch. 675, § 507, as added July 6, 1945, ch. 281, § 3, 59 Stat. 463, and amended Mar. 10, 1947, ch. 16, § 3, 61 Stat. 12; July 13, 1949, ch. 305, § 2, 63 Stat. 409; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F. R. 2053, 67 Stat. 631; Aug. 5, 1953, ch. 334, § 2 (a), (b), 67 Stat. 389.)

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AMENDMENTS

1953—Catchline amended by act Aug. 5, 1953, § 2 (a), to substitute "chlortetracycline" for "aureomycin".

Subsec. (a) amended by act Aug. 5, 1953, § 2 (b), to substitute "chlortetracycline" for "aureomycin".

1949—Catchline amended by act July 13, 1949, § 2 (a), to add "nureomycin, chloramphenicol, or bacitracin".

Subsec. (a) amended by act July 13, 1949, to insert ", nureomycin, chloramphenicol, or bacitracin" following "streptomycin".

1947—Catchline amended by act Mar. 10, 1947, which inserted "or streptomycin" after "penicillin".

Subsec. (a) amended by act Mar. 10, 1947, which inserted "or streptomycin" following "penicillin" in first sentence.

TRANSFER OF FUNCTIONS

All functions of the Federal Security Administrator were transferred to the Secretary of Health, Education, and Welfare and all agencies of the Federal Security Agency were transferred to the Department of Health, Education, and Welfare by 1953 Reorg. Plan No. 1, set out as a note under section 623 of Title 5, Executive Departments and Government Officers and Employees. The Federal Security Agency and the office of Administrator were abolished by section 8 of 1953 Reorg. Plan No. 1.

SUBCHAPTER VI.—COSMETICS

§ 361. Adulterated cosmetics.

A cosmetic shall be deemed to be adulterated—

(a) If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual: *Provided*, That this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: "Caution—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness.", and the labeling of which bears adequate directions for such preliminary testing. For the purposes of this subsection and subsection (e) of this section the term "hair dye" shall not include eyelash dyes or eyebrow dyes.

(b) If it consists in whole or in part of any filthy, putrid, or decomposed substance.

(c) If it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

(d) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

(e) If it is not a hair dye and it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 364 of this title. (June 25, 1938, ch. 675, § 601, 52 Stat. 1054.)

EFFECTIVE DATE

Section 902 (a) of act June 25, 1938, provided that subsections (b)—(e) should take effect twelve months after June 25, 1938, and that subsection (a) should take effect June 25, 1938, except that in the case of a cosmetic to which the proviso of subsection (a) relates, such cosmetic should not, prior to the ninetieth day after June 25, 1938, be deemed adulterated by reason of the failure of its label to bear the legend prescribed in such proviso. Act June 23, 1939, ch. 242, § 1, 53 Stat. 853, provided that the effective date of subsection (e) should be postponed until January 1, 1940.

§ 362. Misbranded cosmetics.

A cosmetic shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(b) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (2) of this subsection reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(c) If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) If its container is so made, formed, or filled as to be misleading. (June 25, 1938, ch. 675, § 602, 52 Stat. 1054; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F. R. 2422, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F. R. 2053, 67 Stat. 631.)

EFFECTIVE DATE

Section 902 (a) of act June 25, 1938, provided that this section should take effect twelve months after June 25, 1938. Act June 23, 1939, ch. 242, 53 Stat. 853, provided that the effective date of subsection (b) should be postponed until January 1, 1940.

TRANSFER OF FUNCTIONS

All functions of the Federal Security Administrator were transferred to the Secretary of Health, Education, and Welfare and all agencies of the Federal Security Agency were transferred to the Department of Health, Education, and Welfare by section 5 of 1953 Reorg. Plan No. 1, set out as a note under section 623 of Title 5, Executive Departments and Government Officers and Employees. The Federal Security Agency and the office of Administrator were abolished by section 8 of 1953 Reorg. Plan No. 1.

See, also, note under section 321 of this title.

§ 363. Regulations making exemptions.

The Secretary shall promulgate regulations exempting from any labeling requirement of this chapter cosmetics which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such cosmetics are not adulterated or misbranded under the provisions of this chapter upon removal from such processing, labeling, or repacking establishment. (June 25, 1938, ch. 675, § 603, 52 Stat. 1054; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F. R. 2422, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F. R. 2053, 67 Stat. 631.)

EFFECTIVE DATE

Section 902 (a) of act June 25, 1938, provided that this section should take effect twelve months after June 25, 1938.

TRANSFER OF FUNCTIONS

All functions of the Federal Security Administrator were transferred to the Secretary of Health, Education, and Welfare and all agencies of the Federal Security Agency were transferred to the Department of Health, Education, and Welfare by section 5 of 1953 Reorg. Plan No. 1, set out as a note under section 623 of Title 5, Executive Departments and Government Officers and Employees. The Federal Security Agency and the office of Administrator were abolished by section 8 of 1953 Reorg. Plan No. 1.

See, also, note under section 321 of this title.

§ 364. Certification of coal-tar colors for cosmetics.

The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in cosmetics and for the certification of batches of such colors, with or without harmless diluents. (June 25, 1938, ch. 675, § 604, 52 Stat. 1055; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F. R. 2422, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F. R. 2053, 67 Stat. 631.)

EFFECTIVE DATE

Section 902 (a) of act June 25, 1938, provided that this section should take effect twelve months after June 25, 1938.

TRANSFER OF FUNCTIONS

All functions of the Federal Security Administrator were transferred to the Secretary of Health, Education, and Welfare and all agencies of the Federal Security Agency were transferred to the Department of Health, Education, and Welfare by section 5 of 1953 Reorg. Plan No. 1, set out as a note under section 623 of Title 5, Executive Departments and Government Officers and Employees. The Federal Security Agency and the office of Administrator were abolished by section 8 of 1953 Reorg. Plan No. 1.

See, also, note under section 321 of this title.

SUBCHAPTER VII.—GENERAL ADMINISTRATIVE PROVISIONS

§ 371. Regulations and hearings.

(a) Authority to promulgate regulations.

The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the Secretary.

(b) Regulations for imports and exports.

The Secretary of the Treasury and the Secretary of Health, Education, and Welfare shall jointly prescribe regulations for the efficient enforcement of the provisions of section 381 of this title, except as otherwise provided therein. Such regulations shall be promulgated in such manner and take effect at such time, after due notice, as the Secretary of Health, Education, and Welfare shall determine.

(c) Conduct of hearings.

Hearings authorized or required by this chapter shall be conducted by the Secretary of Health, Education, and Welfare or such officer or employee as he may designate for the purpose.

(d) Effectiveness of definitions and standards of identity.

The definitions and standards of identity promulgated in accordance with the provisions of this chapter shall be effective for the purposes of the enforcement of this chapter, notwithstanding such definitions and standards as may be contained in other laws of the United States and regulations promulgated thereunder.

(e) Procedure for establishment.

(1) Any action for the issuance, amendment, or repeal of any regulation under section 341, 343 (j), 344 (a), 346 (a) or (b), 351 (b), 352 (d) or (h), 354,

or 364, of this title shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2) of this subsection, the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.

(2) On or before the thirtieth day after the date on which an order entered under paragraph (1) of this subsection is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. Until final action upon such objections is taken by the Secretary under paragraph (3) of this subsection, the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made. As soon as practicable after the time for filing objections has expired the Secretary shall publish a notice in the Federal Register specifying those parts of the order which have been stayed by the filing of objections and, if no objections have been filed, stating that fact.

(3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based. The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

(f) Review of order.

(1) In a case of actual controversy as to the validity of any order under subsection (e) of this section, any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the United States court of appeals for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary thereupon shall file in the court the record of the proceedings on which the Secretary based his order, as provided in section 2112 of Title 28.

(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary, and to be adduced upon the hearing, in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original order, with the return of such additional evidence.

(3) Upon the filing of the petition referred to in paragraph (1) of this subsection, the court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently. If the order of the Secretary refuses to issue, amend, or repeal a regulation and such order is not in accordance with law the court shall by its judgment order the Secretary to take action, with respect to such regulation, in accordance with law. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

(4) The judgment of the court affirming or setting aside, in whole or in part, any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in sections 346 and 347 of Title 28.

(5) Any action instituted under this subsection shall survive notwithstanding any change in the person occupying the office of Secretary or any vacancy in such office.

(6) The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law.

(g) Copies of records of hearings.

A certified copy of the transcript of the record and proceedings under subsection (e) of this section shall be furnished by the Secretary to any interested party at his request, and payment of the costs thereof, and shall be admissible in any criminal, libel for condemnation, exclusion of imports, or other proceeding arising under or in respect to this chapter, irrespective of whether proceedings with respect to the order have previously been instituted or become final under subsection (f) of this section. (June 25, 1938, ch. 675, § 701, 52 Stat. 1055; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F. R. 2422, 54 Stat. 1237; June 25, 1948, ch. 646, § 32, 62 Stat. 991; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F. R. 2053, 67 Stat. 631; Apr. 15, 1954, ch. 143, § 2, 68 Stat. 55; Aug. 1, 1956, ch. 861, § 2, 70 Stat. 919; Aug. 28, 1958, Pub. L. 85–791, § 21, 72 Stat. 948.)

REFERENCES IN TEXT

Sections 346 and 347 of Title 28, referred to in subsection (f) (4) were repealed by act June 25, 1948, ch. 646,

§ 89, 62 Stat. 992, eff. Sept. 1, 1948, and are now covered by section 1254 of Title 28, Judiciary and Judicial Procedure.

AMENDMENTS

1958—Subsec. (f) (1) amended by Pub. L. 85-791, § 21 (a), which substituted provisions requiring transmission of a copy of the petition by clerk to Secretary, and filing of the record by Secretary, for provisions which permitted service of summons and petition any place in United States and required Secretary to certify and file transcript of the proceedings and record upon service.

Subsec. (f) (3) amended by Pub. L. 85-791, § 21 (b), which inserted "Upon the filing of the petition referred to in paragraph (1) of this subsection".

1956—Subsec. (e) amended by act Aug. 1, 1956, to simplify the procedures governing the prescribing of regulations under certain provisions of this chapter.

1954—Subsec. (e) amended by act Apr. 15, 1954, which struck out the reference to section 341 of this title, preceding "343 (j)", such section 341 now containing its own provisions with respect to hearings regarding the establishment of food standards.

CHANGE OF NAME

The Circuit Court of Appeals of the United States was changed to the United States court of appeals by act June 25, 1948, eff. Sept. 1, 1948.)

EFFECTIVE DATE

Section 902 (a) of act June 25, 1938, provided that this section should take effect June 25, 1938.

SAVINGS CLAUSE

Savings clause of act Aug. 1, 1956, which amended subsec. (e) of this section, see note under section 341 of this title.

TRANSFER OF FUNCTIONS

All functions of the Federal Security Administrator were transferred to the Secretary of Health, Education, and Welfare and all agencies of the Federal Security Agency were transferred to the Department of Health, Education, and Welfare by section 5 of 1953 Reorg. Plan No. 1, set out as a note under section 623 of Title 5, Executive Departments and Government Officers and Employees. The Federal Security Agency and the office of Administrator were abolished by section 8 of 1953 Reorg. Plan No. 1.

See, also, note under section 321 of this title.

HEARINGS PENDING ON APR. 15, 1954, WITH RESPECT TO FOOD STANDARDS

Provisions of this chapter in effect prior to Apr. 15, 1954, as applicable with respect to hearings begun prior to such date under subsection (e) of this section, regarding food standards, see note under section 341 of this title.

CROSS REFERENCES

Pesticide chemical regulations, see section 346a of this title.

§ 372. Examinations and investigations.

(a) Authority to conduct.

The Secretary is authorized to conduct examinations and investigations for the purposes of this chapter through officers and employees of the Department or through any health, food, or drug officer or employee of any State, Territory, or political subdivision thereof, duly commissioned by the Secretary as an officer of the Department. In the case of food packed in a Territory the Secretary shall attempt to make inspection of such food at the first point of entry within the United States when, in his opinion and with due regard to the enforcement of all the provisions of this chapter, the facilities at his disposal will permit of such inspection. For the purposes of this subsection the term "United States" means the States and the District of Columbia.

(b) Availability to owner of part of analysis samples.

Where a sample of a food, drug, or cosmetic is collected for analysis under this chapter the Secretary shall, upon request, provide a part of such official sample for examination or analysis by any person named on the label of the article, or the owner thereof, or his attorney or agent; except that the Secretary is authorized, by regulations, to make such reasonable exceptions from, and impose such reasonable terms and conditions relating to, the operation of this subsection as he finds necessary for the proper administration of the provisions of this chapter.

(c) Records of other departments and agencies.

For purposes of enforcement of this chapter, records of any department or independent establishment in the executive branch of the Government shall be open to inspection by any official of the Department duly authorized by the Secretary to make such inspection. (June 25, 1938, ch. 675, § 702, 52 Stat. 1056; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F. R. 2422, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F. R. 2053, 67 Stat. 631.)

EFFECTIVE DATE

Section 902 (a) of act June 25, 1938, provided that this section should take effect twelve months after June 25, 1938.

TRANSFER OF FUNCTIONS

All functions of the Federal Security Administrator were transferred to the Secretary of Health, Education, and Welfare and all agencies of the Federal Security Agency were transferred to the Department of Health, Education, and Welfare by section 5 of 1953 Reorg. Plan No. 1, set out as a note under section 623 of Title 5, Executive Departments and Government Officers and Employees. The Federal Security Agency and the office of Administrator were abolished by section 8 of 1953 Reorg. Plan No. 1.

See, also, note under section 321 of this title.

§ 372a. Examination of sea food on request of packer; marking food with results; fees; penalties.

The Secretary of Health, Education, and Welfare, upon application of any packer of any sea food for shipment or sale within the jurisdiction of this chapter, may, at his discretion, designate inspectors to examine and inspect such food and the production, packing, and labeling thereof. If on such examination and inspection compliance is found with the provisions of this chapter and regulations promulgated thereunder, the applicant shall be authorized or required to mark the food as provided by regulation to show such compliance. Services under this section shall be rendered only upon payment by the applicant of fees fixed by regulation in such amounts as may be necessary to provide, equip, and maintain an adequate and efficient inspection service. Receipts from such fees shall be covered into the Treasury and shall be available to the Secretary of Health, Education, and Welfare for expenditures incurred in carrying out the purposes of this section, including expenditures for salaries of additional inspectors when necessary to supplement the number of inspectors for whose salaries Congress has appropriated. The Secretary is authorized to promulgate regulations governing the sanitary and other conditions under

which the service herein provided shall be granted and maintained, and for otherwise carrying out the purposes of this section. Any person who forges, counterfeits, simulates, or falsely represents, or without proper authority uses any mark, stamp, tag, label, or other identification devices authorized or required by the provisions of this section or regulations thereunder, shall be guilty of a misdemeanor, and shall on conviction thereof be subject to imprisonment for not more than one year or a fine of not less than $1,000 nor more than $5,000, or both such imprisonment and fine. (June 30, 1906, ch. 3915, § 10A, as added June 22, 1934, ch. 712, 48 Stat. 1204, and amended Aug. 27, 1935, ch. 739, 49 Stat. 871; June 25, 1938, ch. 675, § 902 (a), 52 Stat. 1059; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F. R. 2422, 54 Stat. 1237; renumbered § 702A of act June 25, 1938, ch. 675, 52 Stat. 1059 by act July 12, 1943, ch. 221, title II, § 1, 57 Stat. 500, and amended 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F. R. 2053, 67 Stat. 631.)

CODIFICATION

Section, which formerly was not a provision of the Federal Food, Drug, and Cosmetic Act, originally was section 14a of this title. Act June 25, 1938, provided that the section should remain in force and effect and be applicable to the provisions of this chapter. Act July 12, 1943, renumbered this section as 702A of the Federal Food, Drug, and Cosmetic Act.

TRANSFER OF FUNCTIONS

All functions of the Federal Security Administrator were transferred to the Secretary of Health, Education, and Welfare and all agencies of the Federal Security Agency were transferred to the Department of Health, Education, and Welfare by section 5 of 1953 Reorg. Plan No. 1, set out as a note under section 623 of Title 5, Executive Departments and Government Officers and Employees. The Federal Security Agency and the office of Administrator were abolished by section 8 of 1953 Reorg. Plan No. 1.

See, also, note under section 321 of this title.

§ 373. Records of interstate shipment.

For the purpose of enforcing the provisions of this chapter, carriers engaged in interstate commerce, and persons receiving food, drugs, devices, or cosmetics in interstate commerce or holding such articles so received, shall, upon the request of an officer or employee duly designated by the Secretary, permit such officer or employee, at reasonable times, to have access to and to copy all records showing the movement in interstate commerce of any food, drug, device, or cosmetic, or the holding thereof during or after such movement, and the quantity, shipper, and consignee thereof; and it shall be unlawful for any such carrier or person to fail to permit such access to and copying of any such record so requested when such request is accompanied by a statement in writing specifying the nature or kind of food, drug, device, or cosmetic to which such request relates: *Provided*, That evidence obtained under this section shall not be used in a criminal prosecution of the person from whom obtained: *Provided further*, That carriers shall not be subject to the other provisions of this chapter by reason of their receipt, carriage, holding, or delivery of food, drugs, devices, or cosmetics in the usual course of business as carriers. (June 25, 1938, ch. 675, § 703, 52 Stat. 1057; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F. R. 2422, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F. R. 2053, 67 Stat. 631.)

EFFECTIVE DATE

Section 902 (a) of act June 25, 1938, provided that this section should take effect twelve months after June 25, 1938.

TRANSFER OF FUNCTIONS

All functions of the Federal Security Administrator were transferred to the Secretary of Health, Education, and Welfare and all agencies of the Federal Security Agency were transferred to the Department of Health, Education, and Welfare by section 5 of 1953 Reorg. Plan No. 1, set out as a note under section 623 of Title 5, Executive Departments and Government Officers and Employees. The Federal Security Agency and the office of Administrator were abolished by section 8 of 1953 Reorg. Plan No. 1.

See, also, note under section 321 of this title.

§ 374. Factory inspection.

(a) Right of agents to enter premises; notice; promptness.

For purposes of enforcement of this chapter, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (1) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or are held after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.

(b) Written report to owner; copy to Secretary.

Upon completion of any such inspection of a factory, warehouse, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary.

(c) Receipt for samples taken.

If the officer or employee making any such inspection of a factory, warehouse, or other establishment has obtained any sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained.

(d) Analysis of samples furnished owner.

Whenever in the course of any such inspection of a factory or other establishment where food is manufactured, processed, or packed, the officer or employee making the inspection obtains a sample of any such food, and an analysis is made of such sample for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge. (June 25, 1938, ch. 675, § 704, 52 Stat. 1057; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F. R. 2422, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F. R. 2053, 67 Stat. 631; Aug. 7, 1953, ch. 350, § 1, 67 Stat. 476.)

AMENDMENTS

1953—Aug. 7, 1953, amended section generally by designating entire former section as subsec. (a), and by adding subsecs. (b)—(d).

EFFECTIVE DATE

Section 902 (a) of act June 25, 1938, provided that this section should take effect twelve months after June 25, 1938.

TRANSFER OF FUNCTIONS

All functions of the Federal Security Administrator were transferred to the Secretary of Health, Education, and Welfare and all agencies of the Federal Security Agency were transferred to the Department of Health, Education, and Welfare by 1953 Reorg. Plan No. 1, set out as a note under section 623 of Title 5, Executive Departments and Government Officers and Employees. The Federal Security Agency and the office of Administrator were abolished by section 8 of 1053 Reorg. Plan No. 1.

See, also, note under section 321 of this title.

§ 375. Publicity.

(a) Reports.

The Secretary shall cause to be published from time to time reports summarizing all judgments, decrees, and court orders which have been rendered under this chapter, including the nature of the charge and the disposition thereof.

(b) Information regarding certain goods.

The Secretary may also cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health or gross deception of the consumer. Nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department. (June 25, 1938, ch. 675, § 705, 52 Stat. 1057; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F. R. 2422, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F. R. 2053, 67 Stat. 631.)

EFFECTIVE DATE

Section 902 (a) of act June 25, 1938, provided that this section should take effect twelve months after June 25, 1938.

TRANSFER OF FUNCTIONS

All functions of the Federal Security Administrator were transferred to the Secretary of Health, Education, and Welfare and all agencies of the Federal Security Agency were transferred to the Department of Health, Education, and Welfare by section 5 of 1953 Reorg. Plan No. 1, set out as a note under section 623 of Title 5, Executive Departments and Government Officers and Employees. The Federal Security Agency and the office of Administrator were abolished by section 8 of 1953 Reorg. Plan No. 1.

See, also, note under section 321 of this title.

§ 376. Cost of certification of coal-tar colors.

The admitting to listing and certification of coal-tar colors, in accordance with regulations prescribed under this chapter, shall be performed only upon payment of such fees, which shall be specified in such regulations, as may be necessary to provide, maintain, and equip an adequate service for such purposes. (June 25, 1938, ch. 675, § 706, 52 Stat. 1058.)

EFFECTIVE DATE

Section made "immediately effective" by act May 2, 1939, ch. 107, § 1, title I, 53 Stat. 631. It was originally effective twelve months after date of enactment, by section 902 (a) of act June 25, 1938.

§ 377. Revision of United States Pharmacopoeia; development of analysis and mechanical and physical tests.

The Secretary, in carrying into effect the provisions of this chapter, is authorized on and after July 12, 1943, to cooperate with associations and scientific societies in the revision of the United States Pharmacopoeia and in the development of methods of analysis and mechanical and physical tests necessary to carry out the work of the Food and Drug Administration. (July 12, 1943, ch. 221, title II, § 201, 57 Stat. 500; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F. R. 2053, 67 Stat. 631.)

CODIFICATION

Section is from the Labor-Federal Security Appropriation Act, 1944, and not from the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

TRANSFER OF FUNCTIONS

All functions of the Federal Security Administrator were transferred to the Secretary of Health, Education, and Welfare and all agencies of the Federal Security Agency were transferred to the Department of Health, Education, and Welfare by section 5 of 1953 Reorg. Plan No. 1, set out as a note under section 623 of Title 5, Executive Departments and Government Officers and Employees. The Federal Security Agency and the office of Administrator were abolished by section 8 of 1953 Reorg. Plan No. 1.

See, also, note under section 321 of this title.

SUBCHAPTER VIII.—IMPORTS AND EXPORTS

§ 381. Imports and exports.

(a) Imports; examination and refusal of admission.

The Secretary of the Treasury shall deliver to the Secretary of Health, Education, and Welfare, upon his request, samples of food, drugs, devices, and cosmetics which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Secretary of Health, Education, and Welfare and have the right to introduce testimony. If it appears from the examination of such samples or otherwise that (1) such article has been manufactured, processed, or packed under insanitary conditions, or (2) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (3) such article is adulterated, misbranded, or in violation of section 355 of this title, then such article shall be refused admission, except as provided in subsection (b) of this section. The Secretary of the Treasury shall cause the destruction of any such article refused admission unless such article is exported, under regulations prescribed by the Secretary of the Treasury, within ninety days of the date of notice

of such refusal or within such additional time as may be permitted pursuant to such regulations. This subsection shall not be construed to prohibit the admission of narcotic drugs the importation of which is permitted under section 173 of this title.

(b) Same; disposition of refused articles.

Pending decision as to the admission of an article being imported or offered for import, the Secretary of the Treasury may authorize delivery of such article to the owner or consignee upon the execution by him of a good and sufficient bond providing for the payment of such liquidated damages in the event of default as may be required pursuant to regulations of the Secretary of the Treasury. If it appears to the Secretary of Health, Education, and Welfare that an article included within the provisions of clause (3) of subsection (a) of this section can, by relabeling or other action, be brought into compliance with this chapter or rendered other than a food, drug, device, or cosmetic, final determination as to admission of such article may be deferred and, upon filing of timely written application by the owner or consignee and the execution by him of a bond as provided in the preceding provisions of this subsection, the Secretary of Health, Education, and Welfare may, in accordance with regulations, authorize the applicant to perform such relabeling or other action specified in such authorization (including destruction or export of rejected articles or portions thereof, as may be specified in the Secretary's authorization). All such relabeling or other action pursuant to such authorization shall in accordance with regulations be under the supervision of an officer or employee of the Department of Health, Education, and Welfare designated by the Secretary of Health, Education, and Welfare, or an officer or employee of the Department of the Treasury designated by the Secretary of the Treasury.

(c) Same; charges concerning refused articles.

All expenses (including travel, per diem or subsistence, and salaries of officers or employees of the United States) in connection with the destruction provided for in subsection (a) of this section and the supervision of the relabeling or other action authorized under the provisions of subsection (b) of this section, the amount of such expenses to be determined in accordance with regulations, and all expenses in connection with the storage, cartage, or labor with respect to any article refused admission under subsection (a) of this section, shall be paid by the owner or consignee and, in default of such payment, shall constitute a lien against any future importations made by such owner or consignee.

(d) Exports.

A food, drug, device, or cosmetic intended for export shall not be deemed to be adulterated or misbranded under this chapter if it (1) accords to the specifications of the foreign purchaser, (2) is not in conflict with the laws of the country to which it is intended for export, and (3) is labeled on the outside of the shipping package to show that it is intended for export. But if such article is sold or offered for sale in domestic commerce, this subsection shall not exempt it from any of the provisions of this chapter. (June 25, 1938, ch. 675, § 801, 52 Stat. 1058; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F. R. 2422, 54 Stat. 1237; Oct. 18, 1949, ch. 696, §§ 1—3, 63 Stat. 882; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F. R. 2053, 67 Stat. 631.)

REFERENCES IN TEXT

"Section 173 of this title", as used at the end of subsection (a) of this section, originally read, "section 2 of the act of May 26, 1922, as amended (U. S. C., 1934 edition, Title 21, sec. 173)." The act of May 26, 1922, 42 Stat. 596, was an act to amend the act of February 9, 1909, as amended, 35 Stat. 614. Section 173 of this title is based upon section 2 of the act of February 9, 1909, as amended. Section 2 of the act of February 9, 1909, was amended by, and set out as amended in quotation marks in section 1 of the act of May 26, 1922. Section 2 of the act of May 26, 1922, amended sections 5 and 6 of the act of February 9, 1909, which are set out as sections 180 and 182 of this title.

AMENDMENTS

1949—Subsec. (a) amended by act Oct. 18, 1949, § 1, which inserted at end of second sentence ", except as provided in subsection (b) of this section. The Secretary • • • to such regulations.".

Subsec. (b) amended generally by act Oct. 18, 1949, § 2, to provide express statutory authority for the long-standing administrative practice of releasing imported articles that do not comply with the requirements of the law so that they may be relabeled or given appropriate treatment to bring them into compliance.

Subsec. (c) amended generally by act Oct. 18, 1949, § 3, to charge all costs, including salaries and travel and subsistence expenses of officers and employees, against importers.

EFFECTIVE DATE

Section 902 (a) of act June 25, 1938, provided that this section should take effect twelve months after June 25, 1938.

TRANSFER OF FUNCTIONS

All functions of the Federal Security Administrator were transferred to the Secretary of Health, Education, and Welfare and all agencies of the Federal Security Agency were transferred to the Department of Health, Education, and Welfare by section 5 of 1953 Reorg. Plan No. 1, set out as a note under section 623 of Title 5, Executive Departments and Government Officers and Employees. The Federal Security Agency and the office of Administrator were abolished by section 8 of 1953 Reorg. Plan No. 1.

See, also, note under section 321 of this title.

SUBCHAPTER IX.—MISCELLANEOUS

§ 391. Separability clause.

If any provision of this chapter is declared unconstitutional, or the applicability thereof to any person or circumstances is held invalid, the constitutionality of the remainder of the chapter and the applicability thereof to other persons and circumstances shall not be affected thereby. (June 25, 1938, ch. 675, § 901, 52 Stat. 1059.)

EFFECTIVE DATE

Section 902 (a) of act June 25, 1938, provided that this section should take effect twelve months after June 25, 1938.

§ 392. Exemption of meats and meat food products.

Meats and meat food products shall be exempt from the provisions of this chapter to the extent of the application or the extension thereto of sections 71—91 of this title. (June 25, 1938, ch. 675, § 902 (b), 52 Stat. 1059.)

CODIFICATION

Section, as originally codified, consisted of four subsections. Subsection (b) thereof now constitutes this

section. Subsections (a), (c), and (d) of Act of June 25, 1938, related to effective date, repeals, and availability of appropriations.

Chapter 10.—POULTRY AND POULTRY PRODUCTS INSPECTION

§ 451. Legislative findings; authorization of Secretary to designate major consuming areas.

Wholesome poultry products are an important source of the Nation's total supply of food. Such products are consumed throughout the Nation and substantial quantities thereof move in interstate and foreign commerce. Unwholesome and adulterated poultry products in the channels of interstate or foreign commerce, are injurious to the public welfare, adversely affect the marketing of wholesome poultry products, result in sundry losses to producers, and destroy markets for wholesome poultry products. The marketing of wholesome poultry products is affected with the public interest and directly affects the welfare of the people. All poultry and poultry products which have or are required to have inspection under this chapter are either in the current of interstate or foreign commerce or directly affect such commerce. That part that enters directly into the current of interstate or foreign commerce cannot be effectively inspected and regulated without also inspecting and regulating all poultry and poultry products processed or handled in the same establishment.

The great volume of poultry products required as an article of food for the inhabitants of large centers of population may directly affect the movement of poultry and poultry products in interstate commerce. To protect interstate commerce in poultry and poultry products inspected for wholesomeness, from being adversely burdened, obstructed, or affected by uninspected poultry or poultry products, major consuming areas where poultry or poultry products are handled or consumed in such volume as to affect the movement of inspected poultry or poultry products in interstate commerce should be designated by the Secretary pursuant to the provisions of this chapter. (Pub. L. 85–172, § 2, Aug. 28, 1957, 71 Stat. 441.)

EFFECTIVE DATE

Section 22 of Pub. L. 85–172 provided that: "This Act [this chapter] shall take effect upon enactment [August 28, 1957], except that no person shall be subject to the provisions of this Act [this chapter] prior to January 1, 1959, unless such person after January 1, 1958, applies for and receives inspection for poultry or poultry products in accordance with the provisions of this Act]this chapter[and pursuant to regulations promulgated by the Secretary hereunder, in any establishment processing poultry or poultry products in commerce or in a designated major consuming area. Any person who voluntarily applies for and receives such inspection after January 1, 1958, shall be subject, on and after the date he commences to receive such inspection, to all of the provisions and penalties provided for in this Act [this chapter] with respect to all poultry or poultry products handled in the establishment for which such said application for inspection is made."

SHORT TITLE

Congress in enacting Pub. L. 85–172, which comprises this chapter, provided by section 1 of the act that it should be popularly known as the "Poultry Products Inspection Act".

SEPARABILITY PROVISIONS

Section 21 of Pub. L. 85–172 provided that: "If any provision of this Act [this chapter] or the application thereof to any person or circumstances is held invalid, the validity of the remainder of the Act [this chapter] and of the application of such provision to other persons and circumstances shall not be affected thereby."

FOOD ADDITIVES AMENDMENT OF 1958

Section 7 of Pub. L. 85–929, Sept. 6, 1958, 72 Stat. 1789, provided that: "Nothing in this Act [sections 321 (s) and (t), 321 note, 342 note and section 348 of this title, sections 331 (j), 342 (a) and 346 (a) of this title and section 210 (g) of Title 42, The Public Health and Welfare] shall be construed to exempt any meat or meat food product or any person from any requirement imposed by or pursuant to the Poultry Products Inspection Act (21 U. S. C. 451 and the following) or the Meat Inspection Act of March 4, 1907, 34 Stat. 1260, as amended and extended (21 U. S. C. 71 and the following)."

§ 452. Congressional declaration of policy.

It is declared to be the policy of Congress to provide for the inspection of poultry and poultry products by the inspection service as herein provided to prevent the movement in interstate or foreign commerce or in a designated major consuming area of poultry products which are unwholesome, adulterated, or otherwise unfit for human food. (Pub. L. 85–172, § 3, Aug. 28, 1957, 71 Stat. 441.)

§ 453. Definitions.

For purposes of this chapter—

(a) The term "commerce" means commerce between any State, Territory, or possession, or the District of Columbia, and any place outside there-